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Connecticut Medicine

The Journal of the Connecticut State Medical Society

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Industrial Fitness Programs: The Physician's Role

MILTON J. SANDS, JR., M.D., RICHARD R. OSBORN, B.A., CHARLES N. LEACH, JR., M.D., AND ANTHONY S. LACHMAN, M.B.

ABSTRACT – The benefits of programs designed to preserve health through physical fitness are now being recognized by American industry. Physicians by necessity must be involved in such programs to guarantee quality, insure the safety of participants and protect the sponsors from medical liability. Our experiences during the development of a unique low cost, high quality program supervised by a community service organization at industrial work sites in Central Connecticut are discussed, recommendations for preliminary medical screening, medical recertification, and absolute and relative contraindications to participation presented, and methods for cost containment and management of program related problems explained.

The attempt to preserve or restore health through life style modification and strenuous aerobic exercise has developed into a major social commitment in the lives of a rapidly growing number of middle-aged Americans. The potential benefits of this fitness movement have been appreciated within the leadership of the industrial community as management attempts to improve employee job satisfaction, maintain or improve productivity, decrease time loss due to illness and reduce spiralling medical and disability costs. This interest has stimulated a need for structured industrial fitness programs which combine supervised, well balanced aerobic exercise with additional aspects of health maintenance including educational programs directed towards the modification of coronary artery disease risk factors, smoking cessation, stress modification, food selection, weight control, and home and job safety techniques. In response to this need, representatives from local industry, the YMCA (Wheeler Regional YMCA, Plainville, Connecticut) and volunteer physicians met in late 1977 to discuss the possibility of instituting such a program. From this meeting was developed the unique concept for a low cost, high quality fitness program supervised and staffed by a community service organization at the industrial work site.

This paper deals with the physician's responsibilities in the development of this program and the methods used to guarantee the quality of the program, insure participant safety and protect the sponsors from significant medicolegal liability. These responsibilities can best be described by dividing the program into three distinct phases: organization, operation, and re-evaluation.

Organization Phase

During the organizational phase, program responsibilities included both the generation of guidelines for the preliminary medical evaluation and the establishment of minimum health standards for eligibility. The scope of the preliminary examination and in particular, the decision as to the inclusion of some method of stressfully evaluating both exercise capacity and coronary circulation was probably the most controversial issue facing the physician in the development of the program. While attempting to avoid unnecessary preliminary testing with its limited prognostic value, risk of causing physical harm, mental anguish, or economic hardship as a result of an "abnormal" result, and the production of excessive "start-up" costs, the preliminary examination had to be of sufficient depth as to insure both the safety of the applicant and the protection of the sponsors from a program catastrophe. To attain these goals, the medical requirements had to be flexible enough to vary with the applicant's age, current and past medical history, symptomatology, previous physical activity level, and current medication.[1, 2, 3]

Based on the above considerations, current standards of medical practice and the recommendations of certain health fitness organizations,[4] the following guidelines were developed to evaluate candidates for enrollment:

A. *Asymptomatic candidates:*

1. Individuals less than 45 years of age with no known contraindication to participation: history and physical examination administered by a physician knowledgeable in the field of physical fitness and exercise.

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2. Individuals 45 years of age and over: history and physical examination as well as resting electrocardiogram (ECG) followed by fitness evaluation by treadmill exercise testing to 85% of maximum predicted heart rate (220 bpm minus age). This fitness evaluation, preceded by physician review of both resting ECG and completed application, is conducted by the fitness specialist and a registered nurse, both qualified in exercise testing and cardiac resuscitation.

B. *Symptomatic applicants:*
Those with relative contraindication to participation, and those in whom further evaluation is deemed necessary by the screening physician: examination by the appropriate consultant and further testing as recommended. All candidates with suspected or confirmed cardiorespiratory disease are evaluated by a cardiologist and subjected to physician supervised maximum treadmill exercise testing if appropriate.

C. *Rejected applicants:*
In those cases where rejection is based on the presence of cardio-respiratory disease and yet exercise deemed appropriate by both the consulting and primary care physician, enrollment in a cardiac rehabilitation program is offered.

In order to conserve physician time and improve the quality of the historical portion of the screening examination, a health questionnaire is completed by the candidate prior to evaluation and reviewed by the physician during the examination. This questionnaire is designed to detect symptoms of cardio-respiratory, central nervous system or neuromuscular dysfunction, identify significant coronary artery disease risk factors and/or the use of medications capable of compromising participant exercise capacity and safety. (Appendix 1)

Medical eligibility standards for such a program were developed which while stringent enough to exclude persons in whom strenuous physical activity was considered unsafe or contraindicated, were not so restrictive as to deny admission to those individuals in whom the conditioning needs were the greatest. Absolute and relative contraindications to enrollment were generated which excluded participation by the former group while requiring further applicant testing before clearance or disqualification in the latter (Table 1)

Operational Phase

As the program entered the operational phase, all completed applications were reviewed by the physician. Specific attention was directed toward the results of resting electrocardiograms, stress testing material and consultative opinions generated in response to the detection of a particular problem offering a relative contraindication to participation. Following this review, the physician and health fitness specialist jointly developed an individual exercise prescription for each eligible candidate. This prescription, based on a profile drawn from the completed application and incorporating variables such as age, prior exercise experience, current exercise level, significant medical history, limiting medical conditions, and results of stress testing material if available, consisted of a tailored exercise program containing direction as to type, intensity, duration, frequency and progression of aerobic exercise.[4, 5, 6]

Table 1
CONTRAINDICATIONS TO PROGRAM ENROLLMENT

Absolute
1. History of heart disease—symptomatic
2. Presence of uncontrolled cardiac arrhythmia, seizure disorder, hypertension (BP systolic >170 mm.Hg. or diastolic >110 mm.Hg.)
3 Significant acute or subacute illness
4. Cerebral vascular disease

Relative
1. History of heart disease—asymptomatic
2. Presence of controlled cardiac arrhythmia, seizure disorder or hypertension
3. Significant chronic illness or recent (>3 months) surgical procedure
4. Obesity in excess of 25% ideal body weight
5. Bronchial asthma: acute or chronic
6. Pregnancy
7. Musculoskeletal problems limiting exercise include the following:
    a. *acute:*
        fractures, dislocations, tendon or cartilaginous injuries affecting locomotion during the period of injury.
    b. *chronic:*
        any arthritic condition requiring frequent medication and resulting in functional inadequacy of the musculoskeletal system.

Additional responsibilities during the operational phase of the program included provision of continuing medical advice, modification of individual exercise prescriptions mandated by changes in the health of a participant, the production and review of educational programs designed to modify coronary risk factors and promote health and safety, evaluation of new applications for enrollment and, on a quarterly basis, review progress of the participants and the growth of the program in conjunction with the health fitness specialist and industrial representative.

Re-evaluation Phase

As the program matured, it became necessary to develop guidelines for participant medical re-evaluation in order to insure their ongoing health and safety. These guidelines once again incorporated the use of a participant completed health questionnaire designed to detect the presence of significant symptoms, the development of new illness or use of medications which might influence the continued safe participation of the individual without further evaluation. (Appendix 2) In an attempt to contain costs and prevent duplication of testing, the participant was further requested to note the nature and scope of any medical examinations performed within the previous year. These results, if applicable, were requested and reviewed in order to supplement or fulfill the requirements for recertification. (Appendix 3)

Basic guidelines for recertification attempting to balance safety, cost containment and the potential development of both symptomatic and asymptomatic disease during participation in the program were developed and include:

1. All participants are required to complete a recertification questionnaire on a yearly basis. This form is reviewed by the physician in charge of the program;
2. A biennial recertification examination similar to the entrance examination is required of all participants and supplemented in those between the ages of 45 and 55 years of age with resting electrocardiogram and fitness evaluation by treadmill exercise testing to 85% of maximum predicted heart rate;
3. Participants greater than 55 years of age undergo an annual recertification examination, resting electrocardiogram and fitness evaluation as outlined under 2.

Utilization of these guidelines was intended to foster the development of a safe, high quality, on site program at such reasonable cost as to make implementation feasible for most employers regardless of size and budget and therefore, available to all employees regardless of their employment level or responsibility. To date, the safety of the program has been demonstrated as during its four and a half years of existence spanning an estimated 13,000 exercise hours and incorporating over 350 nonphysician supervised exercise tests, there have been no accidents or adverse health effects. Further, the screening program has been successful in detecting disease in both symptomatic and asymptomatic candidates which would limit or restrict participation and in directing those individuals to their physicians for further evaluation and/or treatment. Examples of detected conditions include symptomatic aortic stenosis, moderately severe chronic obstructive pulmonary disease, undetected and poorly controlled hypertension, poorly regulated diabetes, asymptomatic left main and three vessel coronary artery disease, and potentially correctable musculoskeletal dysfunction.

One can only speculate concerning the cost-benefit ratio for detection of disease or modification of risk factors among program participants. By necessity, however, in order to generate an "affordable" program it is mandatory to restrict costs. In this regard certain aspects of our program deserve comment. First, dependent upon the preference of each company, the screening examinations were done by either a company physician or selected local physician. In the former group, the examination fee was contained in the physician's salary while in the latter, the fee was modest as in both circumstances physician time was minimized by preliminary paramedical screening using the health questionnaire to guarantee completeness and exclude examination of persons with major medical illnesses which would necessitate rejection. Second, utilization of recent medical examinations and test results decreased expenses through the prevention of duplicate testing. Third, the time spent in overall physician supervision was modest after the initial program had been developed as the majority of the supervision of the program was done by paramedical personnel and further, physician supervision in this program was donated as a community service. Finally, the cost of initial and recertification stress testing was minimized as these tests were nonphysician supervised and carried out at the YMCA in a low overhead exercise laboratory established for cardiac rehabilitation and industrial fitness programs by donations from local industries and civic organizations. If the latter situation had not existed, the recertification guidelines would have been modified to reflect cost containment by changing the annual recertification requirement of individuals age 55 and over to biennual, relying more heavily on the annual health questionnaire to identify significant problems necessitating individual reevaluation.

During the life of the program, four persistent problems have been identified. First, economic uncertainty: Both additional enrollment and current management interest has been limited by the economic recession. Resolution of this problem awaits an economic recovery. Second, attrition: Participant attrition due to declining interest is a problem universal to fitness programs. Constant motivation of participants by both the sponsor and fitness staff is necessary to minimize this problem. As an example, we found a loss of interest in jogging evidenced by a substantial portion of our female participants could be corrected by the substitution of an aerobic dance program. Third, data management: As enrollment grew and the program matured, it became increasingly difficult to handle participant related information. This problem has grown to the point of threatening to impair the day to day function of the program and necessitated the investigation of computer assisted data management packages. Fourth, ischemic exercise responses: The decision to engage in exercise testing resulted in the detection of a group of asymptomatic persons with an ischemic treadmill exercise response. Our approach to this problem has been to obtain cardiac consultation and maximum supervised exercise testing, in most cases done by the program consultant. (MJS) A decision as to the necessity for further invasive testing to document the presence and severity of disease in this patient population is decided on the basis of the magnitude of the abnormality and its appearance time as well as the preference of the patient and his primary care physician. A unique aspect of this program is that certain of this group of patients could be offered exercise and observation in the cardiac rehabilitation program at the same YMCA.

In conclusion, by describing our experience in the development of a successful industrial fitness program we hope to generate interest in the establishment of similar programs and bring the benefits of fitness to employees at their work site.

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Appendix 1

Medical Certification Health Questionnaire

FOR THE CANDIDATE:

Please read, carefully answer each of the questions and sign application.
Your answers will be treated with strict confidence.

1. Do you have or are you being treated for: (yes/no)

_____ wheezing
_____ shortness of breath
_____ chest pain
_____ palpitations or heart flutter
_____ ankle swelling
_____ dizziness/fainting
_____ bone, back, muscle, or joint problems

_____ heart condition
_____ heart attack
_____ heart murmur
_____ high blood pressure
_____ diabetes
_____ lung trouble: asthma, emphysema, or severe hayfever
_____ stroke, seizure, or fainting spells

2. Do you smoke?_____If so, number of packs/day_____and number of smoking years_____.
3. Are there members of your immediate family age 55 or less with heart disease?_____
If yes, please list relationship and type of problem:______________________________
____

4. Please list current and past serious medical problems:
____
____
____

5. Please list all medications taken regularly: (include birth control pills & non-prescription drugs)

Medication	Dose	Frequency

6. I hereby apply for admission into the YMCA/Company) sponsored Fitness Program. I have no knowledge of any physical disorder which might affect my active participation in this program.
I understand that I may withdraw at any time and agree to undergo a medical examination by a program designated physician to determine my eligibility.

Signature______________________________ Date_________ Home Phone____________________
Name (Print)______________________________ Sex_________ Age_____________
Job Description______________________________ Work Phone_____________
Home address____
Family Physician______________________________ Address____________________________

Sponsoring Industry______________________________

Appendix 2

Medical Recertification Health Questionnaire

FOR THE CANDIDATE:

Please read, carefully answer each of the questions and sign application.
Your answers will be treated with strict confidence.

1. Do you have or are you being treated for: (yes/no)

_____ wheezing
_____ shortness of breath
_____ chest pain
_____ palpitations or heart flutter
_____ ankle swelling
_____ dizziness/fainting
_____ bone, back, muscle, or joint problems

_____ heart condition
_____ heart attack
_____ heart murmur
_____ high blood pressure
_____ diabetes
_____ lung trouble: asthma, emphysema, or severe hayfever
_____ stroke, seizure, or fainting spells

2. Do you smoke?____If so, number of packs/day____and number of smoking years_____.

3. Are there members of your immediate family age 55 or less with heart disease?____
If yes, please list relationship and type of problem:________________________
____

4. Please list all medical problems with specific attention to any problems which have developed since your medical clearance for this program. If you would prefer, list your physician's name and our medical consultant will discuss these with him in strictest confidence.
____
____
____
____

5. Please list all medications taken regularly. (include birth control pills & non-prescription drugs)

Name	Dose	Frequency

6. I have/have not undergone a complete physical examination in the past year. I have/have not had an electrocardiogram. I have/have not had an exercise test. If the answer to this question is yes, please list physician, location, and date.____
____
____

7. I hereby make application for continued participation in the Wheeler Regional YMCA Fitness Program. I understand that participation is voluntary, that I may withdraw at any time, and that medical information obtained in this program will be treated with the strictest of confidence. I acknowledge my responsibility to inform the Program Director of any change in my health status related to or independent of participation in this program. I specifically have no knowledge of any physical disorder which should restrict my participation at this time.

8. Candidate Signature________________________________Sex____________
Candidate Name (Print)______________________________Age____Date______
Work Phone__________________Home Phone____________

Appendix 3

Request for Medical Information

RE: (candidate name) ______________________________________

Dear Doctor,

Your patient is under evaluation to determine eligibility for entry/continued participation in a strenuous exercise program sponsored by (Industry) ________ and the Wheeler Regional Y.M.C.A.

In order to prevent duplication of testing and contain the costs of the program, I would like to review the results of the recent:____________________________________

____

If applicable, on the basis of your recent physical examination (within 1 year) do you find evidence of absolute or relative contraindications to participation?_______
Would you prefer that we re-evaluate the candidate?__________________________
Comments:____

____

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Thank you very much.

Milton J. Sands, Jr., M.D.,
Program Consultant
New Britain General Hospital,
New Britain, Connecticut

Contraindications to Enrollment:

Absolute

1. History of heart disease - symptomatic
2. Presence of uncontrolled cardiac arrhythmia, seizure disorder, hypertension (BP systolic $>$170 mm.Hg. and/or diastolic $>$110.)
3. Significant acute or subacute illness
4. Cerebral vascular disease

Relative

1. History of heart disease - asymptomatic
2. Presence of controlled cardiac arrhythmia, seizure disorder or hypertension
3. Significant chronic illness or recent ($<$ 3 months) surgical procedure
4. Obesity in excess of 25% ideal body weight
5. Bronchial asthma: acute or chronic
6. Pregnancy
7. Musculoskeletal problems limiting exercise of an acute or chronic nature

I authorize transmission of my medical records to Milton J. Sands, M.D. for his review.

CANDIDATE SIGNATURE:______________________________Date_______

Risks in Malaria Prevention: Alternative Prophylaxis with Chloroquine Plus Tetracycline

HANS H. NEUMANN, M.D.

ABSTRACT—For travelers to malarial regions with chloroquine resistant organisms, recommendations call for the prescribing of both chloroquine and Fansidar. Intolerance of Fansidar and adverse reactions to it are increasingly reported in the literature. This and known sensitivity to sulfa drugs can put the physician in a dilemma about what to prescribe. Considering the effectiveness of tetracyclines as adjuvants in the treatment of malaria, we advise, where questions exist about the tolerance of long-acting sulfas, taking a tetracycline (doxycycline) in addition to chloroquine.

The number of countries reporting chloroquine-resistant P. falciparum is increasing and the risk of acquiring an infection is very real for the millions of travelers to the affected regions.

In response to the shifting picture of drug response, CDC, in its recommendations of June 1982[1] regarding the prevention of malaria with chloroquine-resistant P. falciparum in East Africa, suggested a combination of chloroquine with pyrimethamine and sulfadoxine (Fansidar), each to be taken weekly. Regions covered by similar recommendations extend over a growing part of the malarial world, so much so that for American travelers in general, the areas with the need for the combined drug prophylaxis by now outweigh those where chloroquine alone still remains protective. Resistance to chloroquine occurs in much of Middle and South America, East Africa, Southeast Asia and the archipelagos of the Southwest Pacific. Moreover, sporadic resistance to Fansidar as well, by P. falicparum, occurs in Southeast Asia, in parts of Africa and probably South America,[2-5] and can be expected to develop to any antimalarial drug, wherever it is heavily used.

Adverse Effects of Fansidar

Recently, a number of reports appeared in the literature describing serious side effects of Fansidar.[6-9] Both allergic reactions and Stevens-Johnson's syndrome have been observed. Some of these reports question the advisability of a general recommendation of Fansidar for malaria prophylaxis, for reasons of its possible adverse effects. In the experience of our travel clinic, some travelers claimed that they would be unable to take the pyrimethamine/sulfa combination because of mild reactions to test doses which we now suggest. After returning from East Africa, one traveler to whom I had prescribed Fansidar, developed transient hemolytic anemia, presumably linked to the medication. Others gave histories of sensitivity to sulfonamides and Fansidar was therefore not prescribed. This poses unresolved problems on what to advise, since CDC's recommendations do not mention alternatives for such circumstances. The fact that P. falciparum resistance to the pyrimethamine/sulfa combination is spreading, is adding to the difficulties.

The dilemma for the prescribing physician is that he cannot ignore the risk of malaria; yet, he may be more hesitant or reluctant to suggest preventive medication with toxic potential. The manufacturer of Fansidar advises that its use be stopped immediately and medical advice sought if any adverse reactions are suspected; and that periodic blood counts be made if the drug is used preventively for long periods of time.[10]

Problems of Chemoprophylaxis

Physicians have to make decisions in prescribing, based on available knowledge that does not seem to keep pace with the shifting traits of the malaria parasite. Still, the choice of what to prescribe rests with the home-side physician who may have little insight into the specific hazards and risk/benefit ratios.

The problem of chemoprophylaxis is complex, and understandably, recommendations available are in

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general terms. Much as practitioners would like to have dogmatic guidelines, they cannot be provided at this time, comforting though it would be to have them. As the parasite grows more cunning, ongoing trials and a search for new approaches in prevention, are in progress and appear promising. Chloroquine remains the drug of choice where resistant strains are uncommon. It is inexpensive, has a long shelf-life and it can be taken by children and pregnant women. Aside from chloroquine, there appears to be no combination of antimalarial agents that is without risk of serious adverse effects.

Tetracyclines as Adjuncts in Malaria Treatment

The currently available arsenal of malaria-protective drugs is lean. In the *treatment* of chloroquine-resistant falciparum infections, the tetracyclines have been found to be an effective adjunctive agent to quinine, with higher cure-rates than combinations of quinine with pyrimethamine/sulfadoxine.[11-12] This was observed in both Fansidar-sensitive and resistant infections.

This effectiveness of tetracyclines against drug-resistant P. falciparum has been known for many years.[13-15] A study by Colwell and co-workers[13] describes presumptive radical cures with a quinine/tetracycline combination and noted the absence of significant side-effects. Rieckman[14] had similarly good results, and Reacher, Campbell and co-workers[11] compared various drug combinations, and found the combination of quinine with tetracycline more effective in the treatment than when Fansidar was the adjunct. The doses of tetracycline used, 250 mg four times a day for seven days, were relatively small. The action of tetracycline on parasitaemia is slow, but the effectiveness consistent.

Tetracyclines as an Adjunct in Prophylaxis

For prophylaxis, a chloroquine/tetracycline combination should be considered, at least for those unable to tolerate Fansidar. The side effects of tetracyclines are known and relatively benign. Prevention with a q.i.d., or t.i.d. drug regimen would be awkward to follow, and invite poor compliance, particularly if it has to be linked to dietary limitations. The longer half-life in the blood of doxycycline compared with the older tetracyclines, translates into usefulness as a simpler drug regimen. Preventively, it may achieve the desired effects with a once-a-day 100 mg dose. Doxycycline maintains good serum levels for 24 hours, and its absorption from the intestines is not influenced by the intake of food or milk.

Whatever reservations one may have about recommending a tetracycline as preventive medication, these have to be measured against the alternatives. In our clinic, we do not prescribe doxycycline preventively against travelers' diarrhea even though, according to reports in the literature, the once-a-day doses are well tolerated.[16-17] But under problematic circumstances, we do advise, at least for short-term visitors, the taking for malaria prophylaxis of 100 mg of doxycycline daily while in the malarial regions, and for seven days after; this, in addition to chloroquine once-a-week and for six weeks after leaving the area. These drugs should be taken with, or after, the heaviest meal of the day to minimize stomach discomfort.

At first we prescribed the chloroquine/tetracycline combination for travelers who claimed that they were allergic to sulfonamides, and to those who reported some, even minor, side effects to test doses of Fansidar. We now explain the choice and risks, and tend to advise the use of the chloroquine/tetracycline combination in addition to the other known protective measures such as insect repellents, long sleeves, etc. This, so far, has been without failure. However, preventive success in 67 such cases does not demonstrate effectiveness inasmuch as circumstances of exposure vary widely and the statistical probability of travelers to endemic areas acquiring malaria is difficult to assess.

Since tetracyclines, and particularly doxycycline, are concentrated in the liver, they may act in an early phase on the parasite's exo-erythrocytic phase in the liver's parenchymal cells from which the bloodstream is "seeded." This may account for the slower action of tetracyclines in the treatment of malaria if the results are assessed from parasite counts in peripheral blood.

If this is the mechanism of the tetracycline effect on the parasite, then it might be an appropriate prophylactic agent for both P. falciparum and P. vivax, and obviate the need for chloroquine. Yet there are no data available to support such a theoretical conclusion.

Occasionally, tetracycline can itself cause diarrhea or vaginal candidiasis, and it should not be prescribed for pregnant women and children under eight. However, the pyrimethamine-sulfa combination is not recommended either, at least during pregnancy.[1] While there have been few long-term studies of adverse effects of Fansidar, much experience with long-term use of small doses of the tetracyclines exist from their common use in acne and chronic respiratory tract infections.

Preventive medication consumed on a large scale by local residents, in blanket prophylaxis, exerts a selective pressure for the development of drug-resistant strains. This is less likely to happen with a tetracycline because of the frequency with which it would have to be taken for the purpose of prevention.

While the tetracyclines have a good *curative* record in therapeutic combinations, and their usefulness can reasonably be expected for the prevention of malaria, there are, at present, no reliable in vitro methods to test prophylactic drug combinations and their adequacy can only be inferred epidemiologically. With regard to toxicity, the chloroquine/tetracycline combination would appear to be preferable to the triple drug regimen of chloroquine/pyrimethamine/sulfadoxine.

The value of chloroquine/tetracycline for prevention requires confirmation. But this approach, under present circumstances, may represent a useful alternative while the search goes on for acceptable, safe regimens for malarial prophylaxis in areas with resistant P. falciparum.

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Internal Fixation of Femoral Shaft Fractures by a Closed Technique

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ABSTRACT—Intramedullary fixation of femoral shaft fractures by a closed technique using fluoroscopic control was first described over forty years ago in Germany. Recent availability of C-arm fluoroscopy units with image intensification for use in the operating room has rekindled interest in fixation of femoral fractures without operative exposure of the fracture site. During a recent three-year period, fifteen patients were treated by this method at the University of Connecticut Health Center with an average hospital stay of 18.3 days. There were no infections or non-unions. The major advantages of closed nailing over conventional operative techniques for femoral fracture fixation are reduced incidence of infection, more rapid union of the fracture, earlier discharge from the hospital, and improved cosmetic results.

It has been shown conclusively that management of femoral shaft fractures by the operative technique of intramedullary nailing reduces the number of days the patient spends in the hospital, reduces the time to independent ambulation, and reduces time lost from work.[9]

Prior to World War II, most femoral shaft fractures were treated non-operatively by skeletal traction, followed by immobilization in a spica cast. In recent years, the cast brace has become a popular non-operative alternative to nailing, particularly in distal ⅓ fractures.[10] Although this method has little morbidity, it shares with the other non-operative treatments the obvious economic disadvantage of a relatively long hospital stay and long period of convalescence. In one

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comparative series, patients treated by traction and spica cast required an average of 13 months to return to work. Those treated by cast bracing required 8.5 months before return to work. By contrast, patients treated operatively by intramedullary nailing required an average of only five months out of work.[9, 13]

Multiple series have shown intramedullary nailing of femoral fractures to produce less shortening, less angulation, and less frank non-union than other treatment modalities.[3] With the advent of modern orthopaedic surgical techniques and prophylactic antibiotics, infection in intramedullary nailing has become rare. Because of the relative advantages it offers over other methods of treatment of non-comminuted midshaft femoral fractures, intra-medullary nailing has become a common orthopaedic practice. Advances in x-ray equipment and orthopaedic surgical techniques have made possible closed intramedullary nailing, which offers several advantages over the more commonly performed open nailing.

Conventional intramedullary nailing is an "open" procedure. This means that an incision is made over the fracture site, dissection is carried down through the quadriceps muscles, and the fracture is exposed to direct vision. Usually a nail is inserted retrograde out through the proximal femur just medial to the greater trochanter. The fracture is reduced by manipulation of the exposed bone fragments. Then the nail is driven distally to hold the reduction (Figure 1).

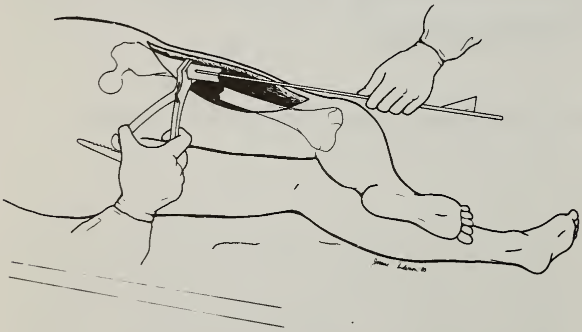

Figure 1
Open nailing. The fracture site is exposed through a generous lateral incision. The guide pin is being inserted retrograde under direct vision.

The "closed" technique of intramedullary nailing, by contrast, does not require an incision over the thigh or direct exposure of the fracture site. Closed nailing is not a new procedure and is performed commonly in many areas of the world. However, it is not a common orthopaedic practice in Connecticut at this time. Closed nailing does offer a number of practical and theoretical advantages over the more commonly used "open" techniques.

The distinct advantages of performing closed nailing relate to not exposing the fracture site. Operative blood loss is less. The closed technique leaves the musculoperiosteal sheath and hematoma undisturbed. The open nailing technique, by contrast, strips away periosteal blood supply and delays healing. Closed reaming of the canal enhances healing by squeezing marrow and bone out through the fracture site, creating autogenous graft material. The risks of infection and chronic osteomyelitis have been clearly shown to be less with the closed technique than with open nailing.[13] Post-operative mobilization is easier and usually quicker.[13, 14] The muscle scarring and adherence to bone which can occur with open nailing is avoided with the closed technique. Knee stiffness is not usually a problem. A further advantage of closed nailing which is readily appreciated by patients, particularly women, is the cosmetically more acceptable scar produced by the closed operation. Usually less than 8 cms in length and lying a hand's breadth above the greater trochanter, it is easily concealed with underwear. By comparison, the open technique leaves a scar extending down the lateral thigh.

The closed technique of femoral nailing was described by Gerhard Kuntscher in a paper presented in Germany in 1940.[8] The cloverleaf-shaped femoral nail used most commonly today bears his name. Partially because of the success with which intramedullary nailing speedily returned injured Luftwaffe pilots to combat, there was a great deal of interest in operative treatment of femoral shaft fractures during and after World War II. However, objections were raised to closed intramedullary nailing in the 1950's because of technical difficulties such as high radiation exposure and jamming of nails, and complications such as infection and non-union.[15] With the advent of flexible intramedullary reaming and modern image intensification fluoroscopy, the closed techniques of Professor Kuntscher once again became popular, particularly in Europe. Among the foremost proponents of closed intramedullary fixation in this country are the group of Kuntscher's disciples at the University of Washington in Seattle, Washington. They have been performing closed nailings since 1967, and report a series of over 600 fractures successfully treated this way.[5] One of the authors of this paper learned the technique at the University of Washington. As a result, the University of Connecticut Orthopaedic Division follows the technique advocated by the Seattle Trauma Center.

At the University of Connecticut Health Center in Farmington, Connecticut, fractures of the femoral shaft are treated by the "closed" method whenever possible. From 1979 through 1982, open nailing has been used only in cases in which concurrent multiple trauma prevented use of the fracture table, when there was major vascular injury present in the same extremity requiring emergent surgical repair, and when there was extensive fracture comminution. This article presents our experience with closed intramedullary nailing of femoral shaft fractures.

Methods

Patients with femoral shaft fractures are placed in balanced skeletal traction with a pin through the proximal tibia or distal femur on admission to the emergency room. This is essential to effect distraction at the fracture site. Otherwise, the fracture will not be reducible at the time of operation due to shortening of the unopposed thigh muscles. Nine to fourteen kg of traction over about five days is usually sufficient to achieve proper alignment. Because femoral fractures are often associated with violent trauma, the patient may require treatment for surgical or medical problems which may be evaluated during the first few days in the hospital. Considerable blood loss around the fracture site is common in femoral fractures. Hematocrit determinations should be performed daily. Arterial blood gases should be drawn on admission as a base-line to monitor for fat embolism syndrome. Scanograms (roentgenograms of the femur taken with a meter stick next to the thigh) are taken to measure the femur for the Kuntscher nail to be used.

All equipment for the operation must be present and working on the day of surgery before the patient is anesthetized. Equipment includes a mobile C-arm fluoroscopic image intensifier with a television monitor and compressed air-driven canulated flexible bone reamers. A full selection of different sized curved Kuntscher nails should be available. The patient is anesthetized in bed in the operating room and then taken out of traction. The patient is then placed in the lateral position on the fracture table with the injured leg in traction. The mobile image intensifier is placed so that anterior-posterior and lateral views may be taken (Figure 2). Only the gluteal area is then prepared and draped. This leaves the unsterile part of the leg free for manipulation. The operation requires the presence of at least two surgeons, one scrubbed and one unscrubbed. Surgeons are shielded with lead aprons because radiation exposure is approximately equivalent to that of a typical gastrointestinal series.

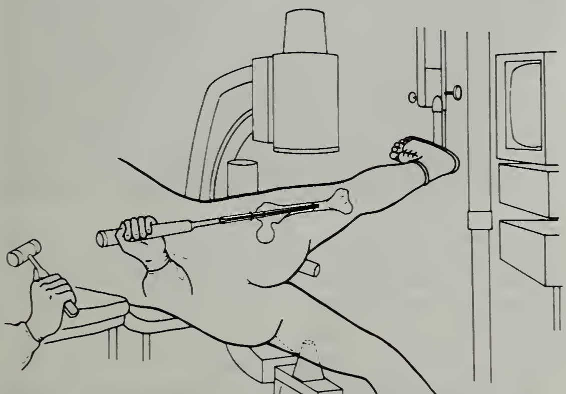

Figure 2
Closed Nailing. The fracture is visualized using a C-arm image intensifying flouroscope with television monitor. Reaming has been done and a Kuntscher nail is being driven across the reduced fracture. Only a small gluteal incision had been made.

The surgeon who remains sterile makes an incision longitudinally proximal to the greater trochanter about 6 to 8 cm long. A muscle splitting incision exposes the medial side of the trochanter. An awl is worked through the bony cortex at the junction of the femoral neck and the greater trochanter. A guide pin is then driven down the femoral medullary canal with a mallet. The unscrubbed surgeon manipulates the fracture site under fluoroscopic control to reduce the fracture. A crutch handle and leather strap are used by the unscrubbed surgeon to achieve reduction of the fracture. The scrubbed surgeon can use a short rod to manipulate the proximal fragment. Once reduced, the guide pin can be tapped across the fracture site using fluoroscopy in two planes. This is generally the most technically demanding part of the operation. The power reamer is then inserted over the guide pin. Reaming is begun at 8 mm and larger-sized reamers are used in 0.5 mm succession. The medullary canal is reamed to 0.5 mm larger than the diameter of the nail selected. Average nail size is about 14 to 15 mm in young males, and 13 to 14 mm in young females. The appropriate size Kuntscher nail is driven distally over the guide wire with the mallet across the fracture site until it reaches a level just proximal to the superior pole of the patella. Proximally, the tip of the Kuntscher nail is allowed to protrude about ½ inch so that the extraction hole is just exposed. The wound is then well irrigated, and gluteal fascia and skin closed.

Post-operatively, the leg is kept in balanced suspension and external rotation is prevented. Assisted active and fully active physical therapy is started after 24 hours. In cases of extreme comminution and instability, skeletal traction is maintained until x-ray evidence of early healing is noted. However, in most cases the patient regains voluntary control of the limb, and balanced suspension is removed within five days. Partial weight bearing and crutch walking is then permitted. Most patients without significant concomitant injuries can be discharged 7 to 10 days post-operatively. Full weight bearing usually begins when the patient feels able to walk without support. However, we try to discourage unprotected weight bearing for about 4 to 6 weeks. At this point, abundant callus is usually seen on x-ray.

The Kuntscher nails are routinely removed about 1 to 2 years after insertion as long as x-ray shows solid union. The nail is removed because future injuries could be complicated by its presence, and because patients sometimes complain of a painful bursa over the proximal part of the nail in the gluteal region. The longer the nail is left in, the more difficult it is to remove it due to bony ingrowth.

Clinical Material

From 1979 through 1982, 15 patients with femoral shaft fractures were treated with closed Kuntscher nailing at the University of Connecticut Health Center. There were 5 women and 10 men. Mean age was 18.8 years with a range of 14 to 25 years. The cause of injury was a motor vehicle accident in 10 cases, and 2 cases were motorcycle accidents. One patient was a pedestrian run over by a motorcycle; one, a cicyclist struck by a car; and one patient fractured her femur in a toboggan accident. All fractures were closed. The type of fracture and its site are shown in Table 1.

Concomitant injuries were found in 9 of the 15 patients. They included other fractures-both open and closed, contusions of heart, lung and kidney, deep lacerations, and hematoma. Associated injuries are shown in Table 2. One patient underwent lateral meniscectomy one month after closed nailing because of clinical evidence of internal derangement of the knee. No knee ligament injuries were noted.

Table 1

CATEGORY OF FEMORAL SHAFT FRACTURES

Type			*Site*
Transverse	11	Middle 1/3	9
Oblique	2	Proximal 1/3	4
Comminuted	2	Distal 1/3	2

Table 2

ASSOCIATED INJURIES

Fracture of acetabulum	3
Fractures of tibia-fibula, open and closed	4
Fractures of spine, stable	1
Kidney contusion	1
Myocardial contusion	1
Pulmonary contusion	1
Closed head injury	1
Pneumothorax	1
Rib fractures	1
Soft tissue injury	5

Results

All patients were followed in the Orthopaedic Clinic of the University of Connecticut Health Center. Follow-up has ranged from one month to two years. Hospital stay ranged from 9 to 31 days with an average of 18.3 days. The longer hospital stays were usually due to the treatment of concomitant injuries. Six patients have had the Kuntscher nail removed following full healing, with an average additional hospital stay of 2 days.

Complications

No infection or non-unions have occurred in our series.

Difficulty with reduction intra-operatively was significant in only one case. In this case, the patient's femur fracture was comminuted with a large lateral butterfly fragment oriented at an acute angle to the shaft. Reduction proceeded with difficulty and ultimately a one inch incision, large enough to admit one finger, was made over the lateral aspect of the thigh. Through this incision, the surgeon was able to guide the guide pin across the fracture site and push the butterfly fragment into position. Because of the degree of comminution of this fracture, two transverse screws, one proximal and one distal, were placed through the predrilled Kuntscher nail to prevent shortening and rotational deformity according to the method of Klemm[6] (Figure 3). Despite concomitant bilateral tibia-fibular fractures, one of which was open, the patient did well. He has since had the nail removed, and is currently able to play Rugby. The most frequent complication in our series was rotational deformity which occurred in 2 of the earliest closed nailings. One patient developed 10 to 15 degrees of external rotation, while another had 5 to 10 degrees of internal rotation. Straight Kuntscher nails were used in the earlier cases. Prebent Kuntscher nails are now used because the natural anatomic anterior bow of the femur is more closely approximated. One of the earlier cases appears to have 5 to 10 degrees more recurvatum than the nonoperative side, resulting from the straight nail used. One patient's surgery was delayed because of fat embolism syndrome. No fat embolism syndromes occurred after surgery.

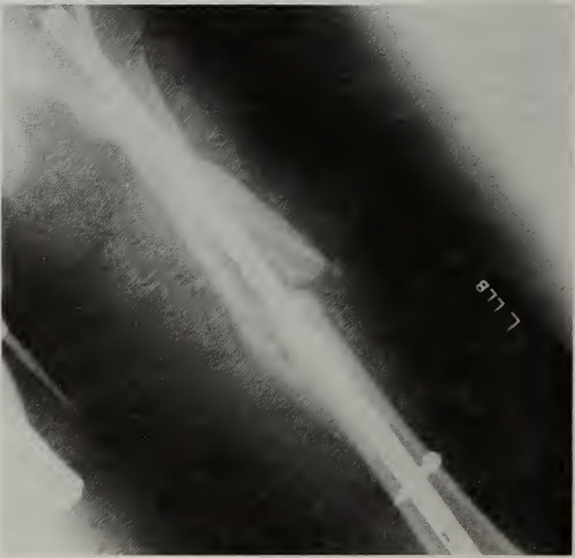

Figure 3

Comminuted fracture fixed by closed intramedullary nailing. Healing at 3 months is advanced as evidenced by abundant callus formation. Transverse interlocking screws were used to prevent shortening and rotational deformity. They were subsequently removed as healing progressed.

Discussion

We believe that most femoral shaft fractures can be treated by closed intramedullary nailing. [13, 14, 17, 18] Contraindications to closed Kuntscher nailing include fractures within 3 cm of the lesser trochanter, severely comminuted fractures, or fractures within 10 cm of the knee. For fractures with extensive comminution we would recommend not reaming and use another form of "internal splintage" such as a flexible nail, or an interlocking Kuntscher nail. In the past year, we treated three cases of severely comminuted femoral shaft fractures not included in this series successfully with flexible Enders nails and short-term traction without opening the fracture site.

The problems of malrotation and shortening can be avoided by attention to detail when positioning the patient on the fracture table, by use of a derotation boot post-operatively, by short-term traction post-operatively, or by use of interlocking nails when comminution is present. Although none of our patients required it, some very unstable fractures may require supplemental external fixation, such as a cast brace, after intramedullary nailing. A more anatomic result is produced by using the newer Kuntscher nail which has a gentle anterior bow like the femur, thus avoiding the apparent increase in recurvatum produced by the older, straight Kuntscher nail.

Two femoral shaft fractures not included in this series occurred in multiply injured patients having arterial lacerations in the fractured extremity. Rapid open nailing coordinated with arterial reconstruction was performed by simultaneously operating teams in each case. Immediate intramedullary nailing facilitates early limb rehabilitation and nursing care in cases of multiple trauma, or severe head injury, but it is not essential for successful arterial grafting. Evidence suggests that immediate stabilization of long bone fractures in multiple trauma patients has the added benefit of reducing the likelihood of acute respiratory distress syndrome and sepsis.[4, 12] We recommend immediate nailing, open or closed, in cases of severe multiple trauma or head injury because stability of fractures may be crucial to keeping the patient alive.

Fat embolism is not a complication of closed intramedullary nailing. Large clinical series support this contention.[5, 12] Experimental work has shown that reaming decompresses the medullary canal so that fat is not forced into the canaliculi, and thus no significant embolization occurs.[2] Fat embolism syndrome occurred in one of our patients, and this occurred pre-operatively. We recommend routinely obtaining arterial blood gases on admission to the emergency room as a baseline to monitor for fat embolism syndrome. We believe a pre-operative waiting period of about 5 days in traction is advisable to monitor the patient's condition, allow hemorrhage at the fracture site to stop, and to allow muscle spasm and shortening to resolve. During this period, periosteal blood supply increases, and healing is probably facilitated by the waiting period.

If technical difficulty with reduction occurs during the operation, we believe it is advisable to make an incision over the fracture site large enough to insert a finger to effect reduction. This useful modification of the closed technique should rarely be necessary. Open epiphyses should never be violated by intramedullary nailing because bone growth can be disturbed. Therefore, it is never used in children. Our youngest patient was 14, but she was skeletally mature. In older adolescents, it should be possible to avoid the greater trochanteric epiphysis and the distal femoral epiphysis in performing a closed nailing. A recent study comparing two groups of adolescents with fractured femurs, one treated with nailing and one treated in traction, showed a clear advantage to nailing.[7]

The results of our small series are representative of the results achieved by other series of closed femoral shaft nailings reported in the orthopaedic literature. The benefits we documented include protection from infection, rapid union, early discharge from the hospital, good functional result, and good cosmetic result. Theoretical and practical advantages of closed intramedullary nailing make it the method of choice for treating most mid-shaft femoral fractures today.

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Rehabilitation of Pediatric Spinal Cord Injury: The Newington Children's Hospital Experience

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ABSTRACT–Children under the age of 16 comprise 5% of the total cases of traumatic spinal cord injury (SCI). Motor vehicular injury is the leading cause of traumatic SCI in the United States whereas diving accidents account for the majority of sports related injuries. Review of 42 cases of spinal cord injury treated at the Newington Children's Hospital indicated that 6 patients with complete and 15 patients with incomplete neurologic lesions demonstrated improvement in one or more Frankel grades of function. Pediatric and adolescent aged victims of traumatic SCI require a specialized, integrated multidisciplinary rehabilitation program in order to achieve maximum restoration of function. The convalescent phase is often complicated due to the high incidence of premorbid behavioral and socioeconomic problems common to this age group. Late spinal deformity is a common consequence of SCI in the skeletally immature patient which frequently requires appropriate external orthotic support followed by spinal fusion when skeletal maturity is attained.

There are approximately 8,000 new cases of traumatic spinal cord injury each year in the United States. Although the average age at the time of injury is 29 years, according to information from the national model spinal cord injury data base; only 5% of the victims are under 15 years of age at the time of injury.[1] During the past decade numerous children and adolescents have been referred to Newington Children's Hospital for rehabilitation following acute spinal cord injury. This review summarized the current status of rehabilitation of spinal cord injury in the child and adolescent.

Based upon analysis of 18 northern Californian counties, in 1970-1971, Kewalramani et al.,[2] identified 58 cases of spinal cord injury in children under 16 years of age which represented 9.4% of the total recorded cases of spinal cord injury. The mortality at injury was high, as 34 of the 58 patients died, 13 of them within 20 minutes of injury. Based upon their experience, it was projected that approximately 1,065 children per year in the United States would sustain acute spinal cord injury with approximately 550 children surviving to hospital admission with a further 20% succumbing in the period of acute hospitalization.

The automobile is the primary etiological factor in pediatric and adolescent spinal cord injury. Vehicular injuries accounted for 60% of all cases as reported by Kewalramani. It was the major factor in a series of 29 patients reported by Burke,[3] and accounted for 21% of injury in a series of 156 cases reported by Anderson and Schutt.[4]

According to DeVivo,[5] the main life expectancy for spinal cord injury victims is 30.2 years. Modified life expectancy tables were devised based upon the current, epidemiologic, and demographic data. From this it is estimated that the life expectancy of a male 10 years of age at the time of discharge from the hospital with an incomplete paraplegia is 57.2 years compared to 59 years for the general population. Life expectancy drops to 42 years for complete paraplegia, 49 years for incomplete quadriplegia, and to 28.6 years for complete quadriplegia. Higher mortality rates are linked to the greater incidence of chronic renal and cardiopulmonary disease in patients with higher levels of complete paralysis.

Forty-two cases of spinal cord injury were treated at the Newington Children's Hospital within the past ten years. All patients were referred for rehabilitation or spinal stabilization from other acute care hospitals within the New England region. There were 27 males

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and 15 females ranging in age from birth to 23 years. Twenty-two patients were in the age range 14-19, 9 were age 10-14 years, and 6 were age 5-9 years. Two children were under age 5. Three patients were young adults aged 20-23 years. (Table 1)

Table 1
AGE AT INJURY

Birth	1
1-4	1
5-9	6
10-14	9
15-19	22
20-23	3

Trama was the causative factor in 39 of the 42 cases whereas one patient sustained vascular infarct and 2 children developed paralysis secondary to neoplasia. Eighteen cases (46%) were caused by motor vehicular injury including one case of thoracolumbar fracture dislocation in a 16-year-old male who fell from, and was subsequently run over by a golf cart. There were 10 cases caused by diving accidents and 2 injuries of the cervical spine from football, (Table 2). There were 3 cases of penetrating injuries all caused by hand guns.

Table 2
ETIOLOGY OF SPINAL CORD INJURY

Automobile		13
Motorcycle		2
Golf Cart		1
Auto-Pedestrian		2
Diving Injuries		10
Gunshot Wound		3
Football		2
Fall		5
Vascular infarct		1
Tumor		2
Ewings	(1)	
Dermoid	(1)	
Birth Trauma		1
		42

Twenty-four of the 42 cases demonstrated complete neurologic injuries whereas 18 sustained incomplete injury. The neurologic status of all patients was assessed on admission and compared to their neurologic status at discharge according to the method of Frankel,[6] (Table 3). Fifteen of the patients demonstrating improvement in one or more Frankel grades had incomplete neurologic injuries including 5 cases of central cord syndrome, 2 patients with Brown Sequard syndrome, and 7 patients with mixed root cauda equina injury associated with fracture dislocation at the thoracolumbar junction. An additional 6 patients with complete lesions demonstrated improvement of one level of nerve root function due to recovery from peripheral nerve root injury at the level of cord damage ("root escape").

The average length of stay for patients in this series range from 2 months for thoracic and lumbar level injuries to 4.8 months for cervical level injuries. Three patients required additional operative procedures for incomplete reduction, short fusion, or technically inadequate instrumentation for fracture dislocations of the thoracolumbar spine. Of the 39 patients aged 19 or younger, 11 (29%) demonstrated post-traumatic paralytic scoliosis and 2 developed kyphosis at the site of posterior decompression and laminectomy. Ten of the 13 patients developed scoliosis or kyphosis before skeletal maturity and 1 patient with a T-8 paraplegia with a mild idiopathic scoliosis prior to injury developed progressive scoliosis following standard posterior fusion and instrumentation of a fracture dislocation of the mid-thoracic spine.

Table 3
COMPARISON OF NEUROLOGIC STATUS AT INJURY VERSUS DISCHARGE

Neurological Lesion at Discharge

Neurological Lesion At Injury	A	B	C	D	E
A	14	2	1	1	
B		2	3	3	
C			1	9	
D				5	1
E					

Neurological Status
A-Complete Loss Motor & Sensory
B-Sensory Only Present
C-Motor Useless
D-Motor Useful
E-Recovery

Case Report

Many of these patients have associated medical problems complicating their rehabilitation care as exemplified by the following case report:

An 11-year-old caucasion male sustained a compression fracture subluxation of C4 on C5 resulting in immediate complete quadriplegia at the C4 level on 10/8/80. Following posterior cervical fusion, he was transferred to Newington Children's Hospital for acute rehabilitation. The patient developed severe immobilization hypercalcemia (6.1-6.7 milli equivalents) with accompanying irritability, lethargy, and nausea which slowly responded to a therapy regimen of calcitonin, lasix, saline diureses and oral phosphates. Because of fever of unknown etiology before surgical stabilization, a renal scan demonstrated no function of the right kidney, although repeat urinalyses were negative for infection. On 3/9/81, the patient developed spiking fevers of 103.5 degrees fahrenheit and a large hydronephrotic kidney was noted on intravenous pyelogram. Following emergency percutaneous nephrostomy on 3/11/81 the infection was controlled and a right nephrectomy was performed on 3/17/81. Operative findings revealed a congenital ureteropelvic obstruction with severe hydronephrosis and a superimposed acute pyelonephritis.

The patient completed his rehabilitation program becoming independently mobile with a chin controlled electric wheelchair, and adept at typing, drawing and reading with a mouth control stick, (Figure 1). A sip-puff environmental control system was installed in his room at home for control of lights, intercom communications, television, radio and bed control. He was subsequently discharged on 6/10/81. Following discharge, the patient resumed a regular school schedule but developed a progressive paralytic right thoracic scoliosis which rapidly progressed to 45 degrees. On 8/19/82, he underwent a posterior fusion with segmental instrumentation which provided sufficiently rigid fixation to allow postoperative mobilization without body cast or orthosis. His fusion has healed and he is currently completing the 9th grade while awaiting special education in computer technology for enhanced communication skills. (Figure 2)

Discussion

Traumatic spinal cord paralysis is a catastrophic injury in the child and adolescent. In addition to all of the medical problems of adult spinal cord injury, there are unique medical and social problems in these younger patients. In young children, complete spinal cord lesions are often accompanied by minimal or no radiologic signs of vertebral injury. Burke [3] reported this disassociation in 80% of a series of 29 children with complete cord injuries. He concluded that longitudinal traction may be a major factor in the pathogenesis of these injuries. The one infant in this series presented with a T3 level paraplegia following a double footling breech presentation with completely normal spinal x-rays.

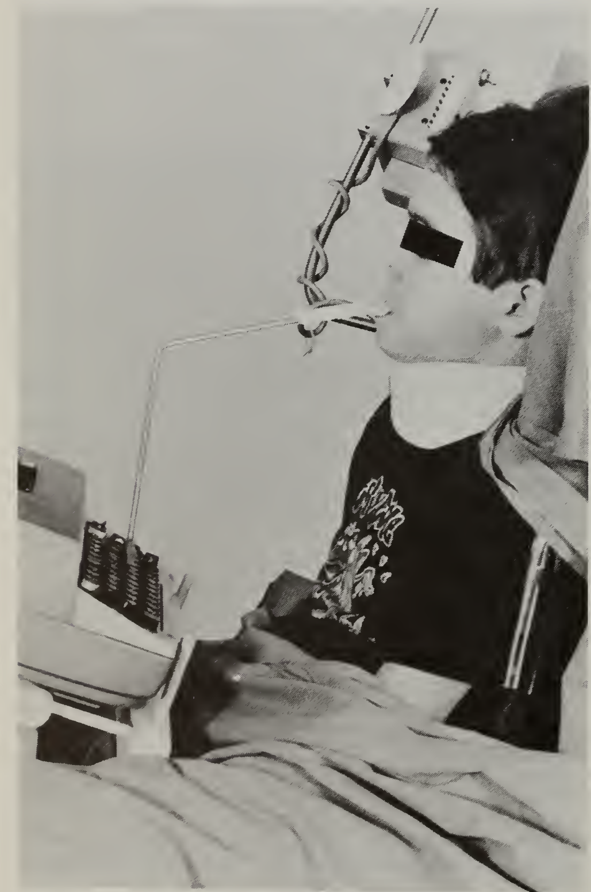

Figure 1

C-4 total quadraplegic following posterior cervical fusion demonstrating typing skills with customized mouth stick. The chin controlled auto drive device for his electric wheelchair is temporarily swung out of the way.

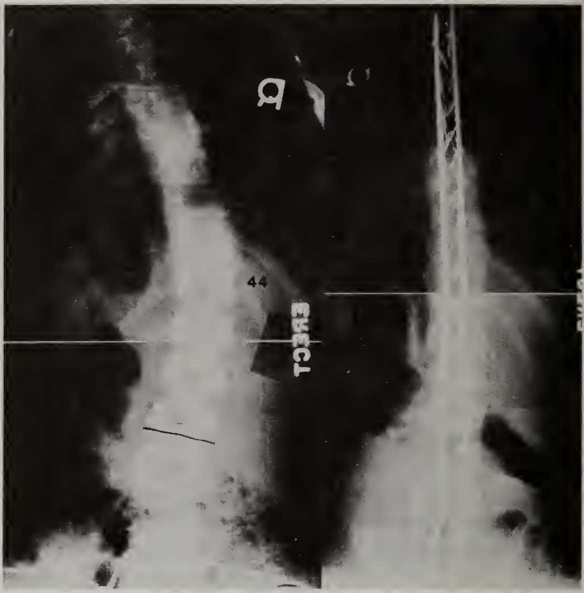

Figure 2

(Left) PA roentgenogram of the spine demonstrates a right thoracolumbar paralytic scoliosis measuring 44° which progressed rapidly during the first 10 months post injury.

(Right) PA roentgenogram of the spine following fusion with sublaminar segmental wire fixation to the contoured "L" shaped rods which are secured to the pelvis.

The problem of hypercalcemia, although rare, is most often reported in cases of adolescent males who become totally immobilized due to their injury during a period of rapid bone growth.[7] Although hypercalcemia may also occur in older patients with extensive Pagets disease, the young active male with balanced but elevated rates of bone accretion and reabsorption is at risk in case of sudden total immobilization. Symptoms may be vague, ranging from gastrointestinal symptoms of anorexia, nausea and vomiting to dehydration and emotional instability. The condition must be differentiated from primary hyperparathyroidism. Normal levels of immuno reactive parathyroid hormone help differentiate the two conditions in approximately 80% of reported cases.[8] Rationally, treatment should include rapid mobilization of the patient which is obviously hampered in cases of high tetraplegia. Hypercalcemia can be controlled by the infusion of large amounts of intravenous fluids, and calcitonin. Glucocorticoids are beneficial probably by reducing the rate of bone reabsorption.[8] Frequent monitoring of serum calcium levels during convalescence will allow the clinician to identify this problem before serious calcium inbalance occurs. Progressive late spinal deformity is common in patients sustaining paraplegia prior to skeletal maturity.

Progressive kyphosis resulting from instability following wide decompression laminectomy is well recognized.[3] One patient in this series developed significant kyphosis following "decompression" laminectomy at T12 for an incomplete lesion which required subsequent spine fusion. In retrospect, coordinated neurosurgical and orthopaedic treatment at the time of initial injury could have prevented this late problem.

Late paralytic scoliosis is well recognized.Campbell and Bonnett[9] reported an incidence of 91% spinal deformity in a group of 64 juvenile patients. They claimed greatest risk for progressive deformity in females under age 12 and males under 14 years of age. Lencourt, Dickson, and Carter,[10] in a series of 50 patients aged 0-17 years noted 31 with scoliosis greater than 20 degrees. The risk of scoliosis was present in all levels of paralysis, however, the patient's age at injury and the presence of spasticity were the major contributing factors. Mayfield, et al[11] reviewed 49 patients under 18 years of age. The 28 juvenile patients injured before puberty all developed scoliosis, kyphosis or lordosis and 61% required fusion. Seventy one percent of the 21 adolescent patients developed scoliosis and ⅓ of this group required fusion.

Thirty percent of the patients in this series demonstrated scoliosis. All children are treated with light weight custom molded polypropylene total contact thoracolumbosacral spinal orthoses. Although scoliosis in this group is inevitable, orthotic management improves spinal support and sitting balance and postpones spinal fusion until the majority of spinal skeletal growth is completed. Adolescent patients must be observed closely and treated with orthoses when appropriate. Paralytic scoliosis may progress rapidly as illustrated in the detailed case report. Although scoliosis is uncommon in patients injured following skeletal maturity, preexisting idiopathic curves of mild degree may progress and require surgical stabilization. This was well illustrated in the case of an 18-year-old female with a T8 paraplegia whose mild idiopathic scoliosis progressed following operative reduction and limited fusion at the time of injury. In both cases, the improved technique of segmental fixation allowed optimum correction, rigid internal fixation, and improvement in postoperative management without the necessity of cast or brace immobilization. Avoidance of prolonged recumbancy and restricted turning activity is of utmost importance in these patients with high levels of paraplegia and quadriplegia who are at increased risk for skin breakdown and pulmonary problems.

The second leading cause of spinal cord injury in the National Registry is sports (16%) of which⅔ are due to diving injuries.[1] Of 25 cases of quadriplegia in this series, 10 were directly caused by diving accidents. The mechanism of injury in most cases was one of axial loading of the cervical column in flexion as the victim dived into shallow depths in either swimming pools or open water. Unfortunately, the majority of sports related cord injuries involve water sports in other countries as well. Sir Ludwig Guttman, in 1976, described 74 of 111 cases due to diving and emphasized that only "systematic education of the public generally" will afford a reduction of this unacceptably high injury rate.[12]

The management of thoracolumbar fracture dislocations deserves special mention. As outlined recently by Davies et al.,[13] there is no demonstrable improvement in neurologic function in cases treated by operative reduction and fusion compared to the more conservative techniques of closed reduction and recumbancy advocated throughout the British commonwealth. The major advantage in operative reduction and spinal fixation is a reduction in the length of hospitalization. Five patients in the present series underwent operative reduction, instrumentation and fusion of thoracolumbar fracture dislocations, however 2 of these patients required reoperation for complications of incomplete reduction of the fracture site and inadequate fixation with Harrington distraction rods. The most common error as described by Dickson is that of inadequate length of instrumentation and he emphasized that the distraction hooks must be placed two interspaces above and two interspaces below the facture interspace.[14]

It is imperative that surgeons undertaking reduction and instrumentation of cases of acute spinal cord injury be thoroughly versed in the demanding operative techniques. The rate of reoperation for these patients can only be lowered by either strict adherence to the surgical prerequisites or by referral of such patients to centers skilled in the care of spinal trauma.

Spinal cord injury in the growing child or adolescent pose special medical, surgical, and social problems. In addition to the often catastrophic functional loss are superimposed the additional problems of continued physical and emotional growth, basic education, personality development, family relationships and vocational training. Numerous late adolescent patients in this series posed serious challenges in attaining realistic and rewarding rehabilitation goals, due in large part to premorbid behavioral problems including drug and ethanol abuse, criminal behavior and deteriorated family structure. This is in distinct contrast to Anderson's 28-year review in a rural area where such social problems were "remarkably absent."[4] Reports from other urban centers confirmed the fact that the pre-existing social problems further complicate the rehabilitation process for such children.

The successful rehabilitation program for the child and adolescent must include the interdisciplinary care of not only physicians and allied health specialists but in addition social service, educational, recreational, and psychological services to meet the special needs of these patients.

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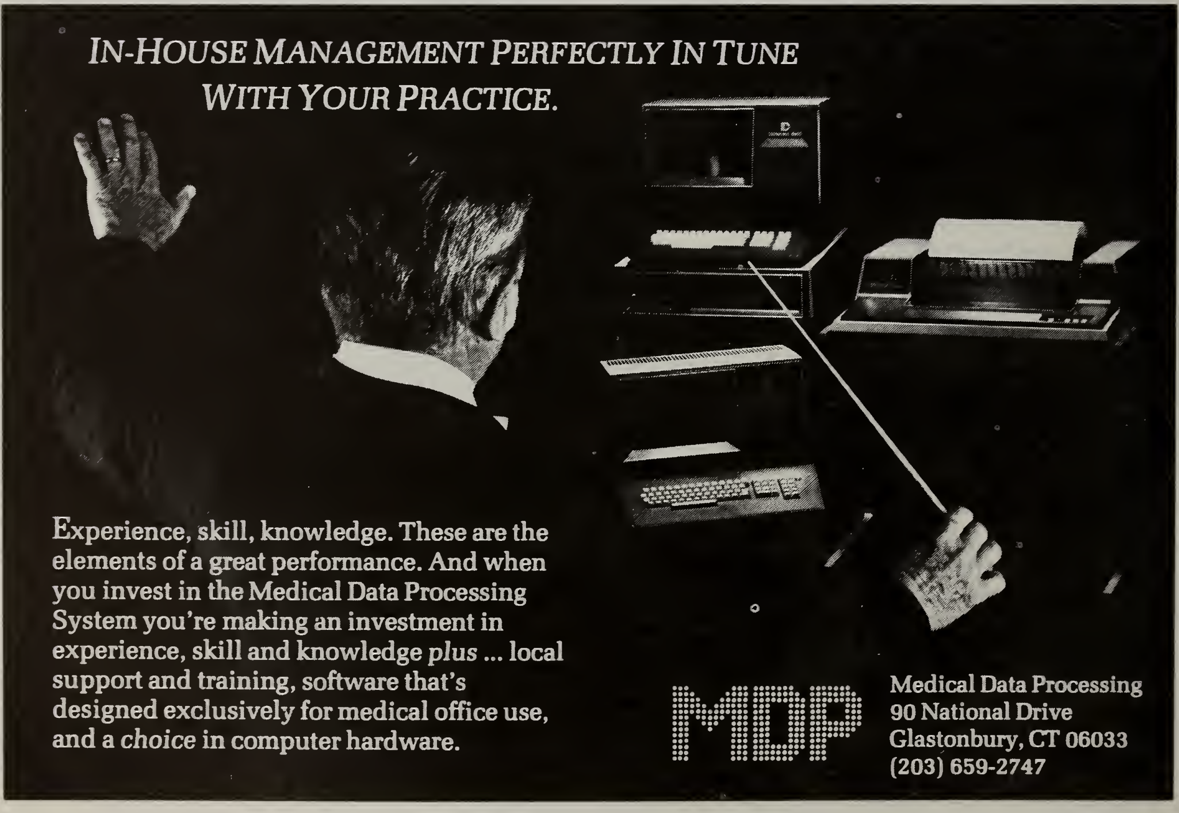

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Important Advances in Clinical Medicine

Epitomes of Progress—Dermatology

Sunscreens

The sunburn effects of ultraviolet light on epidermal DNA are well documented, and whereas a definite cause and effect relation between such damage and skin carcinogenesis is not certain, DNA damage induced by ultraviolet-B is thought to be an important component. An ideal sunscreen should protect against all biologic effects of ultraviolet radiation and not simply inhibit ultraviolet-induced skin erythema.

There have been recent attempts to evaluate sunscreens using different assay procedures. The standard human assay procedure is called the human sun protection factor (SPF) assay. Using volunteers, the minimal erythemal dose is determined in their skin where not previously exposed to sun by administering a series of dose increments of ultraviolet radiation using usually a solar-simulator light source. The next day, areas of skin are treated with the sunscreen to be tested and the ultraviolet radiation again delivered. The sun protection factor is calculated as the ratio of the minimal erythemal dose in protected skin to the minimal erythemal dose in unprotected skin.

Many commercially available sunscreens have sun protection factor readings of 15; this means that a person can stay in the sun for 15 times the length of time that would produce skin erythema without the sunscreen.

Sunscreens containing para-aminobenzoic acid (PABA) and its esters have been shown to protect against ultraviolet-induced changes in epidermal DNA synthesis rates in hairless mice. They have also been shown in hairless mice to protect against photocarcinogenesis.

Whereas definitive information on the ability of sunscreens to protect against photocarcinogenesis in humans is not yet available, logic tells us that these sunscreen preparations are highly likely to inhibit photocarcinogenesis and possibly photoenhanced aging in human skin.

The recommendation must be that all persons, particularly those with light skin, should use sunscreens routinely and regularly when spending time exposed to the sun.

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Acyclovir and Herpes Simplex

Acyclovir (acycloguanosine; 9-[(2-hydroxyethoxy) methyl]guanine; Zovirax, Burroughs Wellcome Co.) is emerging as but one of a new generation of specific antiviral chemotherapeutic agents that are potent inhibitors of herpesvirus, the organisms that cause herpes simplex types 1 and 2, herpes zoster and varicella. The selectivity of the drug is due to the fact that cells harboring the herpesvirus contain thymidine kinase, an enzyme that transforms acyclovir into acycloguanosine triphosphate. Uninfected cells lack thymidine kinase and acycloguanosine triphosphate, a potent inhibitor of viral DNA polymerase, forms in herpes-infected cells at 40 to 100 times greater concentration than uninfected cells. The drug has a low index of toxicity for humans. Acyclovir has been licensed by the Food and Drug Administration in both topical and intravenous forms for treatment of a first episode of herpes simplex in both healthy and immunocompromised patients.

Double-blind controlled trials of topical acyclovir in primary genital herpes have shown a shorter period of viral shedding, less pain and faster healing of lesions compared with findings in controls. No significant difference was observed in these data, however, in patients with the recurrent form of herpes simplex. Because of this and the potential for resistant strains of the virus emerging, it has been advised that acyclovir not be given topically for recurrent genital herpes.

Preliminary studies of orally given acyclovir have generally shown reduced periods of viral shedding, time to crusting and time to complete healing in patients with primary herpes simplex. But whereas symptomatic recurrences of herpes can be successfully suppressed by taking the drug, oral administration of acyclovir did not prevent later recurrence of disease. Intravenous use of acyclovir is selectively indicated for treating a severe first episode of herpes because viral shedding is reduced from an average of eight to two days; likewise, the drug represents a substantial advance in the care of immunosuppressed patients with the recurrent form of mucocutaneous herpes.

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Diagnosis of Primary Melanoma

Although it is much feared, malignant melanoma is almost completely curable if diagnosed early. Fortunately it most often occurs in superficial locations and has a characteristic appearance. It generally arises de novo on otherwise normal skin, albeit a significant number of lesions arise in preexisting nevi. There are several useful clinical signs that should alert a physician to the possibility of such a tumor. These include changes in size, border and surface and irregular color.

Any irregularly pigmented lesion is suspicious. Most superficial spreading melanoma, which accounts for more than 70 percent of such lesions, will show not only brown and black but also varying shades of red, white and blue. White relates to areas of regression in a tumor, whereas red is due to inflammation. Blue discoloration is more ominous because it suggests pigment present deeper in the dermis. Nodular melanoma is often uniformly bluish black, slate gray or bluish red. Early in their course, lentigo maligna melanoma and acral lentiginous melanoma often have only enlarging brownish discoloration and later show the other characteristic colors.

Most melanoma spreads slowly on the surface of the skin. The initial erratic growth creates an irregular border. The periphery of the lesions is angulated, indented or notched. This is often the first clue. An exception is nodular melanoma, which is smooth margined.

Irregularity of surface is also seen in relatively early lesions. Areas of scale or alteration in surface skin markings may be noted. Most benign nevi are less than 1 cm in diameter. Lesions larger than this or those showing any of the above signs are suggestive.

If diagnosed early, melanoma is amenable to curative surgical treatment more limited in extent than previously thought. Waiting for the late signs such as bleeding, crusting, ulceration or nodule formation will result in a poor prognosis.

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Kaposi's Sarcoma: Current Trends

In 1872 Moritz Kaposi described the occurrence of smooth reddish skin nodules in six men. The characteristics of the disease, later to be named Kaposi's sarcoma, included a predilection for the lower extremities, multifocal presentation with lesions in the viscera and histologic features characterized by hemorrhage and hemosiderin deposition. This classic form of Kaposi's sarcoma is now known to occur most frequently in elderly men of Italian or Jewish descent and to be characterized by chronic indolent nodules on the lower extremities accompanied by lymphedema.

Almost 100 years after Kaposi's original description, two other groups were found to be susceptible to this disease. Kaposi's sarcoma occurs relatively frequently in equatorial Africa, accounting for 9 percent of malignant conditions in Uganda. In addition to the indolent variety, several aggressive forms with extensive lymph node involvement have been identified in African blacks. A similarly fulminant type of Kaposi's sarcoma has been described in patients with renal transplants and in those receiving immunosuppressive therapy.

In July 1981 the Centers for Disease Control reported cases of Kaposi's sarcoma among homosexual men. Many patients were reported to have had an illness characterized by fever, weight loss and lymphadenopathy preceding the appearance of skin lesions. This fulminant form of Kaposi's sarcoma is occurring in persons with immunosuppression as manifested by cutaneous anergy, the presence of opportunistic infections such as *Pneumocystis carinii* pneumonia, lymphopenia and a decreased ratio of circulating T helper-to-T suppressor lymphocytes. A similar syndrome has been identified in Haitians and intravenous drug abusers.

The current epidemic has sparked numerous investigations. The neoplastic cell is probably derived from vascular endothelium as has been shown by immunoperoxidase staining for factor VIII, a vascular endothelial marker. In addition, a pathogenic role for cytomegalovirus has been suggested by the finding of cytomegalovirus antigens in tumor tissue by immunofluorescence and by the identification of cytomegalovirus RNA in tumor cells by in situ cytohybridization. This epidemic provides a unique opportunity to further investigate the relationship between genetics, environment, immunology, cancer and infections.

Clinicians should be alert to the current epidemic. Skin lesions can present as single or multiple reddish purple macules, nodules or plaques on any location of the skin or mucous membranes. Unlike classic Kaposi's sarcoma, the upper torso and upper extremities may be predominantly afflicted. These lesions may resemble hemangioma or dermatofibroma so that histologic examination is necessary to establish a diagnosis.

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Ketoconazole

Ketoconazole is a new antifungal drug that may become the drug of choice for the treatment of most fungal infections. It is effective against a wide range of mycotic diseases. Its broad spectrum of activity, the ease and convenience of oral administration, its safety and its lack of resistance by an organism indicate a potential unequaled by other drugs and modalities.

Ketoconazole is an imidazole that inhibits ergosterol synthesis by interrupting the demethylation of lanosterol. The drug is fungistatic and appears to be synergistic with host cells. It is indicated for treatment of blastomycosis, candidiasis, coccidioidomycosis, histoplasmosis, chromomycosis and paracoccidioidomycosis. Further, it is effective in treating the entire spectrum of dermatophyte infections, pityriasis versicolor and mycetoma due to *Petriellidium boydii.* The drug is also effective in treating leishmaniasis. Because gastric acidity is required for dissolution, antacids, anticholinergics and hydrogen-2 blockers such as cimetidine should not be given concomitantly. They may be administered two hours after ketoconazole. An achlorhydric patient should be given a 200-mg ketoconazole tablet dissolved in 4 ml of aqueous solution of 0.2N hydrochloric acid. The solution can be added to fruit juice and drunk through a straw, followed by a cup of tap water.

The drug has not been shown to interact with oral anticoagulants or hypoglycemic agents nor has it shown carcinogenic or mutagenic effects. It has some teratogenicity when given to rats at ten times the dose for humans.

Adverse reactions have been rare and usually mild, of a nature seldom causing cessation of therapy. In rare instances idiosyncratic hepatitis has been reported to occur, with a possible incidence of 1 in 10,000 patients. As a result, liver function studies should be considered if therapy is to be prolonged. Even more important, patients should be seen at periodic intervals and their condition clinically evaluated by the prescribing physician. With rare cases of idiosyncratic hepatitis being reported, a physician should check a patient for nausea, weakness, vomiting, abdominal pain or jaundice. Any abnormalities should be further evaluated and reported and the drug therapy discontinued.

Ketoconazole also lowers the serum testosterone level and depresses adrenocorticotropic hormone stimulation. At the recommended dosage, however, this is not significant, and the levels return to normal within 24 hours. Occasionally gynecomastia has been reported to occur in male patients who have been receiving long-term therapy; it is transient, however, an escape phenomenon of gland function, and disappears even with continuation of therapy.

In summary, ketoconazole is an effective broad-spectrum antifungal agent that has the convenience of oral administration and rare side effects. No resistant organisms have been reported, despite more than eight years of worldwide use.

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Immunotherapy and Bleomycin in the Treatment of Recalcitrant Warts

Human warts are caused by species-specific 55-nm large DNA icosahedral papillomaviruses of at least eight different antigenic subtypes. The host response to wart infection involves both humoral and cell-mediated immune responses, but the cell-mediated system seems particularly important in the phenomena of wart rejection and spontaneous regression.

In a recent review of the immunobiology and treatment of warts. Rees notes that a safe and effective vaccine, while long awaited, is still unavailable and that research on wart viruses continues to be hampered by the lack of suitable culture techniques and the difficulty of finding a virus in most types of warts. Moreover, the spontaneous regression of warts in about two thirds of all cases within two years of inception reinforces the fact that aggressive treatment should be reserved for long-standing infections truly recalcitrant to traditional treatment modalities. Two relatively recent and effective modes of therapy, one involving the induction of cell-mediated immunity and the other the direct inoculation of an antimetabolic substance, are described below.

Dinitrochlorobenzene is a potent sensitizer and a known mutagen but is not carcinogenic. Treatment involves sensitization via topical application of a 1 percent to 2 percent concentration of dinitrochlorobenzene in acetone solution and subsequent repeated applications of weaker concentrations (0.05 percent to 0.5 percent) of dinitrochlorobenzene in acetone or aquaphor solution to all involved sites at daily to weekly intervals. Sanders and Smith reported that the above approach resulted in complete clearing in more than 80 percent of patients with warts resistant to standard therapy. The major side effects are local erythema and irritation at the site of application of the dinitrochlorobenzene.

Another highly effective treatment for resistant warts is the intralesional injection of bleomycin sulfate. In a series involving more than 1,000 warts, Shumack and Haddock found a 93 percent cure rate within four weeks. A 0.1 percent solution was used, with the volume limited to 0.1 ml in any individual site, with no total dose larger than 2 mg. The major side effects are moderate local pain and burning at the injection site and local pigmentary changes.

These two treatments are important additions to the armamentarium of therapy for recalcitrant human warts. They each have above-average cure rates but should nonetheless be reserved for carefully selected cases because they are not without drawbacks in terms of cost and discomfort to patients.

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Pemphigus: An Autoimmune Mucocutaneous Disease

Pemphigus is an intraepidermal blistering disease occurring on skin and mucous membranes (for example, the mouth, esophagus and vagina). It is the result of loss of normal cohesion between epidermal cells. The findings of recent studies in two aspects of pemphigus have important clinical implications: compelling evidence suggesting the pathogenetic role of pemphigus autoantibodies and evidence of drug-induced pemphigus.

The evidence of supporting the pathogenetic role of the pemphigus autoantibodies has been the correlation of pemphigus antibody titers in serum and the activity of the disease; the observation of neonatal pemphigus passively transferred from an affected human mother, and the finding that organ cultures of specimens of normal human skin in the presence of pemphigus antibody developed histologic changes similar to that of naturally occurring pemphigus. Added to the above evidence is the report in 1982 of success in passive transfer of pemphigus from human to laboratory animals. The results of the experiments using intraperitoneal injection of neonatal mice with various concentrations of serum from patients with pemphigus indicate a direct relation between the degree of acantholysis with the titer of pemphigus antibody. In 1982 the antigen(s) to which pemphigus antibodies bind has been characterized as a cell-surface glycoprotein synthesized by human and mouse keratinocytes. Thus, investigations in recent years have convincingly established pemphigus as an autoimmune disease.

The in vitro studies in recent years also provide a great deal of evidence suggesting that pemphigus antibody, in the absence of complement, activates a proteolytic enzyme(s) that in turn causes the destruction of normal cell-to-cell cohesion. Pemphigus appears to be a unique type of autoimmune epidermal injury that does not require the participation of complement.

The clinical importance of these new findings is that the therapy should be directed primarily at reducing the level of pemphigus antibody in affected patients. The administration of systemic corticosteroids and immunosuppressive agents is (still) the treatment of choice. Other modalities of reducing pathogenetic antibodies such as plasmapheresis have been attempted and require further investigation.

D-Penicillamine-induced pemphigus has been increasingly observed—49 cases have been reported in the literature, most of them in the past five years. These cases have characteristic histologic and immunofluorescent features of pemphigus and a close time sequence between the penicillamine administration and the onset of the disorder. This is another example of a drug-induced autoimmune disease through its mechanism is unknown at the present time. The widespread use of penicillamine for connective tissue disorders indicates the monitoring of its side effects should include pemphigus.

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Pyoderma Gangrenosum

Pyoderma gangrenosum is an ulcerative skin disorder of unknown cause. Since its description in 1930, little progress has been made in our understanding of the pathogenesis of this disease. However, cumulative clinical experience has provided much information about diagnosis, disease associations and treatment.

The earliest recognizable lesion in this disease is an erythematous papule, nodule or pustule. This early lesion subsequently ulcerates and may enlarge rapidly in a few days until arrested by therapy, it may progress for a longer time—from weeks to months—or it may spontaneously involute. An established ulcer is recognized by its edematous, violaceous and serpiginous border. The ulcer enlarges peripherally and is characteristically undermined at the margin of diseased and normal skin. Lesions most commonly affect the lower extremities, though all body sites can be involved. Lesions characteristically develop at sites of trauma (for example, biopsy sites).

An association between pyoderma gangrenosum and ulcerative colitis is well established. When these two disorders occur together the activity of the skin disease usually parallels that of the bowel disease. Associations between pyoderma gangrenosum and classic rheumatoid arthritis, a seronegative rheumatoidlike arthritis and the arthritis of inflammatory bowel disease have been recognized. Other important but less common disease associations include regional enteritis (Crohn's disease), chronic active hepatitis, plasma cell dyscrasia, leukemia and myeloproliferative syndromes. Pyoderma gangrenosum occurs without an apparent disease association in about half the cases.

The diagnosis is clinical and rests on the morphologic appearance of an ulcer, its clinical behavior and the presence of an associated disease. Histopathologic findings are not diagnostic but provide supportive evidence for a diagnosis. A biopsy in suspected cases is essential to rule out other mimicking disorders (for example, deep mycoses and atypical mycobacterial infections). Immunofluorescent study of biopsy specimens from an ulcer margin has shown perivascular deposition of IgM, C3 and fibrin in a number of cases. The specificity of this finding and its ultimate use as a diagnostic tool have yet to be established.

Local ulcer care, including careful debridement, and elevation and rest of the affected site are important. Antibiotic therapy should be directed at any associated infection; administration of systemic corticosteroids is the most effective form of treatment. High doses of prednisone, in the range of 80 to 120 mg a day, are frequently required. Sulfones and sulfapyridine are useful for treating steroid-resistant disease or for use as steroid-sparing agents in chronic recurrent disease. Clofazimine, an antimycobacterial agent with antiinflammatory properties, and immunosuppressive agents, particularly azathioprine, have also been used successfully in recalcitrant cases.

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Warts Are Important, Too

Human papillomavirus is capable of producing a number of clinically distinct epithelial neoplasms. Previously these clinical characteristics were thought to be determined by the anatomic site where the wart developed, rather than by the virus itself. With improvements in immunofluorescence and immunoperoxidase technology, it appears that there are as many as eight immunologically distinct human papillomaviruses. To a large extent, their antigenic differences reflect their clinical appearance. For example, papillomavirus types 1 and 4 are associated with plantar warts, type 2 with common warts, type 3 with flat warts, type 6 with genital warts and type 7 with butcher's warts.

Papillomavirus type 5 is associated with a rare familial disease called epidermodysplasia verruciformis. In those afflicted, warty neoplasms develop over much of the skin. These tumors tend to degenerate into squamous cell carcinoma. Recently, using DNA hybridization techniques, DNA sequences characteristic of papillomavirus type 5 have been found in a number of squamous cell carcinoma lesions from such patients.

Others have linked genital warts (type 6) with cervical cancer. On the basis of histologic evidence, an unusual condition of the cervical epithelium has been described that is believed to be due to a "subclinical infection" by the papillomavirus. There is compelling statistical evidence that this histologic change is causally related to cervical neoplasia.

Bowenoid papulosis of the genitalia is a newly recognized neoplasm consisting of multiple 3- to 10-mm pigmented papules on the external genital. Because of its disturbing histologic appearance, there is concern over its malignant potential. Both ultrastructural and immunologic evidence has recently pointed to the existence of papillomavirus in these lesions.

Further investigation into host-parasite relationships in papillomavirus-induced neoplasms should be productive. At the very least, we have learned that the wart is not in the least bit "common."

Gary W. Cole, M.D.

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Dysplastic Nevus Syndrome

Dysplastic nevi were first reported to occur in association with familial malignant melanoma, which accounts for 1 percent to 6 percent of the total cases of melanoma. The presence of such atypical nevi has been designated the "B-K mole" syndrome based on the initials of the surnames of two families originally studied. These lesions occurred in 18 of 20 (90 percent) patients with familial melanoma and 24 of 43 (56 percent) first-degree relatives. Since this report, the occurrence of dysplastic nevi has also been observed in patients with nonfamilial melanoma. As clinical and histologic features of dysplastic nevi in a familial or sporadic context are similar, the following nomenclature has been proposed: dysplastic nevus syndrome, sporadic type, or dysplastic nevus syndrome, familial type. Recognition of such precursor lesions to melanoma may serve to identify patients at risk for this malignancy. Careful follow-up with photographic documentation and biopsy of lesions suggesting malignant transformation are important so that lesions may be surgically removed at an early, curable stage.

Characteristically, dysplastic nevi are larger in size (more than 5 mm) than ordinary acquired nevi and have an irregular color and outline. Although shades of tan or brown predominate, there may be pinkish hues and slight scaling depending on the degree of inflammation. Dysplastic nevi range in number from a single lesion to 200 or more, and occur on covered as well as sun-exposed areas of the body. Lesions continue to develop throughout adult life. Histologic features include atypical intraepidermal melanocytic hyperplasia, dense dermal lymphocytic infiltration with fibroplasia and increased vascularity.

A polygenic inheritance of precursor nevi has been proposed because of the large number of affected persons in melanoma-prone families and the high frequency of sporadic atypical moles occurring in up to a third of cases of nonfamilial melanoma. A transition between ordinary and precursor nevi has been considered; environmental factors may play a role in their expression. Such factors may include ultraviolet light, hormonal changes or alterations in host immunity. The report of melanocytic atypism occurring in pigmented macules on the buttocks following photochemotherapy for psoriasis with psoralen and ultraviolet-A (ultraviolet light in 320- to 400-nm wavelength range) raises the concern that dysplastic nevi may be produced. The influence of immunologic factors is suggested by the rapid development of invasive melanoma in 14 immunosuppressed renal transplant recipients, of whom seven showed dysplastic nevi.

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Naturally Acquired Leprosy in Animals

Because of changing patterns of immigration, leprosy is becoming more common in the United States. This increase has resulted in a number of articles designed to stimulate an awareness in practicing physicians of leprosy as a diagnostic possibility in their patients. In addition, leprosy has been found to occur spontaneously in animals.

For many years leprosy, like smallpox or chickenpox, was considered to be transmitted exclusively from humans to humans, without animal reservoirs. Beginning in 1974 a lepromatous leprosylike illness was recognized in feral armadillos *(Dasypus novemcinctus)*. This illness was identical to that seen in captive armadillos inoculated with human *Mycobacterium leprae* and the etiologic agent could not be distinguished from human *M leprae*. In Louisiana examination of tissues from more than 1,000 armadillos showed rates of infection ranging from 4 percent to 30 percent. Infected armadillos have also been identified in Texas and in the San Diego Zoo in California. A survey of 451 armadillos in Gulf Coast counties of Texas found an overall infection rate of 4.6 percent, range 0 percent to 15.4 percent (Dr. Jerome Smith, personal communication). A study by the Centers for Disease Control found no association between leprosy patients in Louisiana and exposure to armadillos. However, a case of lepromatous leprosy was diagnosed in a patient who had killed and dressed an armadillo.

In 1977 naturally acquired lepromatous leprosy was recognized in a chimpanzee. In 1979 a lepromatous leprosylike illness was identified in a "sooty" Mangabey monkey captured in Nigeria. Subsequently lepromatous leprosy developed in captive sooty Mangabey monkeys following inoculation with human *M leprae* harvested from armadillos. Also bacteria from the index case have produced lepromatous leprosy when inoculated into armadillos and other sooty Mangabeys.

Thus there is little reason to doubt that lepromatous leprosy may occur naturally in animals. The importance and significance of these observations are not settled. The possibility that these animals acquired their disease from human material cannot be excluded. However, it also cannot be excluded that these illnesses were acquired from other animals or from the soil. The case of the armadillo dresser suggests that transmission may occur from animal to human. Thus, the old concept that leprosy is exclusively transmitted from human to human is being challenged.

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Carbon Dioxide Laser Treatment in Dermatology

The carbon dioxide laser is being used increasingly in clinical dermatology. The following is a brief description of the properties that make the instrument particularly well suited for specific dermatology applications.

The term laser is an acronym for *l*ight *a*mplification by *s*timulated *e*mission of *r*adiation. The radiation is coherent, meaning that its component waves have a uniform wavelength, are generated in phase and follow an almost parallel path. The carbon dioxide laser emits radiation at 10,600 nm, which is in the far infrared range of the electromagnetic spectrum. The beam target size is 2.3 mm when unfocused and used for tissue vaporization; it is about 0.2 mm when focused and used as a scalpel.

At typically used power settings, exposure times and skin-to-laser distances, the laser beam causes instantaneous vaporization of tissue by heating intracellular water to a temperature of 100 °C. This vaporization occurs to a depth of 0.1 to 0.2 mm, and this depth can be varied by adjustment of power settings and exposure times. Hardly any of the thermal energy is scattered from the target to surrounding tissues. This means that only one to two layers of cells adjacent to the vaporized area are damaged by conducted thermal energy. These properties permit the instrument to directly vaporize epithelial lesions or excise them with minimal trauma to surrounding skin and its appendages. Hemostasis is achieved by thermal sealing on impact of vessels up to 0.5 mm in diameter. Nerve endings are sealed in the same way resulting in less postoperative pain compared with other surgical techniques.

The carbon dioxide laser has been applied to the Mohs surgical procedure, a procedure for microscopically controlled excision of skin cancer. A surgeon can choose to vaporize tissue or excise it for frozen-section evaluation; very thin horizontal sections may be removed with minimal artifactual disruption of histologic features and maximal preservation of critical anatomic areas. Thin layers of cartilage or bone can be removed easily if tumor has invaded these structures. Lymphatics and small vessels are sealed automatically, helping to prevent tumor spread.

Port wine stains and other vascular skin abnormalities are well suited for carbon dioxide laser treatment. In carefully selected patients, laser therapy selectively coagulates and seals the dilated vessels that make up these lesions, sparing the surrounding normal tissue. Before the laser treatment, options were unsatisfactory.

Tattoos respond poorly to removal attempts using dermabrasion and surgical excision, but the laser is sometimes more successful. Pigments that extend into the dermis are selectively vaporized. Again, because of the unique properties of the laser, destruction of normal tissue is minimal, bleeding is negligible, postoperative pain is decreased and scarring is less likely.

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Surgical Treatment of Primary Malignant Melanoma

Although still evolving, the surgical treatment of primary malignant melanoma is much less extensive than several years ago. Since 1907 it has been generally accepted that whenever such a lesion is excised, 5-cm borders be removed regardless of depth of invasion. More recent information from several melanoma centers has refuted the need for such generous margins and in fact suggests the adequacy of minimal margins.

A sensible approach to surgical treatment takes into account the depth of invasion as well as the site of the tumor. These take precedence over other factors including the type of melanoma: superficial spreading melanoma, nodular melanoma or lentigo maligna melanoma. Any lesion invading less than 0.85 mm is adequately treated with surgical margins of up to 1.5 cm of clinically normal skin whereas lesions invading more than 1.69 mm are excised with a 3-cm margin. The location of tumors 0.85 to 1.69 mm thick determines their treatment. Such lesions arising in higher risk sites—the upper back, posterolateral arms, posterior and lateral neck and posterior scalp—are treated by taking larger margins whereas lesions up to 1.69 mm thick in any other site are treated by the more conservative excision.

Whether or not to remove underlying fascia is an area of controversy; recent evidence suggests it is not necessary. There are proponents of the use of grafts, flaps and primary direct closure. Again the evidence seems to indicate that the less scarring procedures are satisfactory.

There is no consensus regarding node dissection. The most recent prospective studies show no improvement in survival for those who undergo node dissection at the time of initial surgical procedure compared with those who have dissection only when clinically palpable nodes develop. Although initial studies showed a tendency toward slightly improved survival with node dissection in those with deep melanoma, no statistically significant difference was found. On longer term followup even this tendency was not apparent. Therefore the most recent evidence indicates prophylactic node dissections are unnecessary.

These more limited surgical guidelines do not unfavorably affect prognosis. As the surgical techniques for melanoma come under closer scrutiny, further changes in recommendations will be forthcoming.

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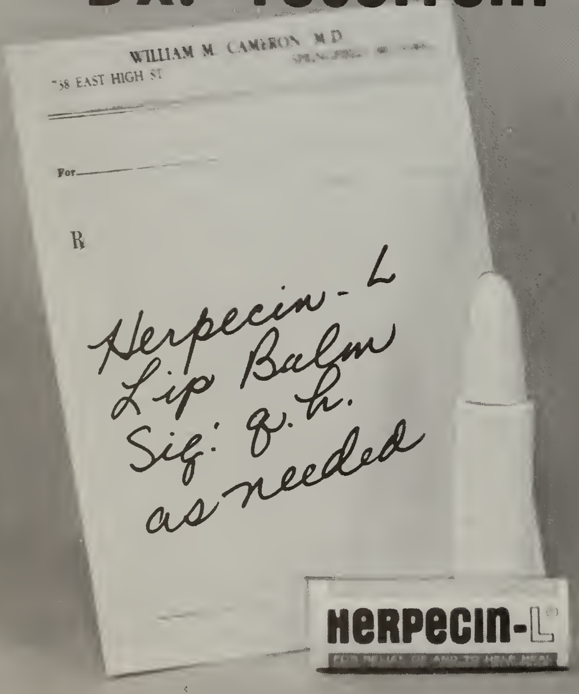

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Liver Transplantation

NATIONAL INSTITUTES OF HEALTH

Introduction

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summmaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

Since performance of the first human orthotopic liver transplantation in 1963, over 540 such operations have been carried out in four medical centers in the United States and Western Europe. Additional liver transplantation procedures have been performed in other parts of the world, and more recently in several other American medical centers. Although extremely demanding and expensive, the operation has been shown to be technically feasible, and interpretable results have been reported from all four primary transplant centers. These clearly demonstrate that liver transplantation offers an alternative therapeutic approach which may prolong life in some patients suffering from severe liver disease that has progressed beyond the reach of currently available treatment and consequently carries a predictably poor prognosis. However, substantial questions remain regarding selection of patients who may benefit from liver transplantation; the stage of their liver disease at which transplantation should be performed; survival and clinical condition of patients beyond the initial year after transplantation; and overall long-range benefits and risks of transplantation in the management of specific liver diseases.

In order to resolve some of these questions, the National Institutes of Health on June 20-23, 1983, convened a Consensus Development Conference on Liver Transplantation. After 2 days of expert presentation of the available data, a Consensus Panel consisting of hepatologists, surgeons, internists, pediatricians, immunologists, biostatisticians, ethicists, and public representatives considered the offered evidence to arrive at answers to the following key questions:

1. Are there groups of patients for whom transplantation of the liver should be considered appropriate therapy?
2. What is the outcome (current survival rates, complications) in different groups?
3. In a potential candidate for transplantation, what are the principles guiding selection of the appropriate time for surgery?
4. What are the skills, resources, and institutional support needed for liver transplantation?
5. What are the directions for future research?

1. Are there groups of patients for whom transplantation of the liver should be considered appropriate therapy?

Liver transplantation is a promising alternative to current therapy in the management of the late phase of several forms of serious liver disease. Candidates include children and adults suffering from irreversible liver injury who have exhausted alternative medical and surgical treatments and are approaching the terminal phase of their illness. In many forms of liver disease the precise indications and timing of liver transplantation remain uncertain or controversial.

Prolongation of life of good quality for patients who would otherwise have died has been reported in following conditions:

From the Office of Medical Application of Research, National Institutes of Health, Bethesda, Md.

Reprint requests to the Office of Medical Applications of Research, Room 216, National Institutes of Health, Bethesda, MD 20205 (Michael J. Bernstein).

- *Extrahepatic biliary atresia* is the most common cause of bile duct obstruction in the young infant. Patients who fail to respond to hepatoportoenterostomy (Kasai procedure) often benefit from liver transplantation. Recent data suggest that as many as two-thirds of these patients survive for 1 year or more after transplantation.

- *Chronic active hepatitis* is caused by viral infections or drug reactions, but many cases remain unexplained. Some patients with progressive liver failure are candidates for transplantation. Currently, exceptions seem to include drug-induced chronic active hepatitis, which usually responds to removal of the chemical agent, and hepatitis B-induced disease in which viremia persists. In the latter instance, rapid reappearance of infection with progressive liver failure has been reported following transplantation.
- *Primary biliary cirrhosis is* a slowly progressive cholestatic liver disease. Results of transplantation appear favorable for patients with end-stage liver injury. The procedure may improve the quality of life.
- *Inborn errors of metabolism* may cause end-stage liver damage or irreversible extrahepatic complications. Transplantation may be appropriate for such patients.
- *Hepatic vein thrombosis* (Budd-Chiari syndrome) often results in progressive liver failure, ascites, and death. Patients who have not responded to anticoagulation or appropriate surgery for portal decompression may be candidates for transplantation.
- *Sclerosing cholangitis,* a chronic non-suppurative inflammatory process of the bile ducts, may cause liver failure. Less favorable results following transplantation in this group may be due to prior multiple surgical procedures, a diseased extrahepatic bile duct, the presence of biliary infection, or other factors.
- *Primary hepatic malignancy* confined to the liver but not amenable to resection may be an indication for transplantation. Results to date indicate a strong likelihood of recurrence of the malignancy. Nonetheless, the procedure may achieve significant palliation.
- *Alcohol-related liver cirrhosis and alcoholic hepatitis* are the most common forms of fatal liver disease in America. Patients who are judged likely to abstain from alcohol and who have established clinical indicators of fatal outcome may be candidates for transplantation. Only a small proportion of alcoholic patients with liver disease would be expected to meet these rigorous criteria.

Although *fulminant hepatic failure* with massive hepatocellular necrosis induced by hepatitis viruses, hepatotoxins, or certain drugs may warrant liver transplantation, rapid progression of the disease and multi-organ system failure frequently preclude this option.

2. What is the outcome (current survival rates, complications) in different groups?

The survival and complication rates of patients who have undergone liver transplantation are the major criteria for judging efficacy. Data are available from four locations (Pittsburgh; Cambridge, England; Hanover, Germany; and Groningen, The Netherlands). The interpretation of the existing data on survival is extremely difficult because no control data are given for comparison, surgical techniques and drug therapies varied over time, and patient selection criteria and management differed across centers.

While sufficient data for thorough assessment of liver transplantation are not available to date, today certain trends appear to emerge:

- Patients currently being accepted for transplantation have a high probability of imminent death and a low quality of life in the absence of transplantation.
- Patients undergoing transplantation have an operative mortality (within 1 month) of 20 to 40 percent.
- One-year survival among transplant recipients since 1980 is favorable when compared with their expected course in the absence of transplantation.
- Since 1980, 1-year survival appears improved over the earlier transplant experience.
- Individual patients have survived for many years with good quality of life after transplantation.
- Data are insufficient to evaluate survival rates beyond 1 year following transplantation with current technologies.
- Short-term quality of life is probably enhanced in many transplant survivors. We lack systematically gathered information on quality of life among long-term survivors.

Severe non-lethal complications of transplantation frequently occur and must be taken into account in judging efficacy of this procedure.

Massive hemorrhage is the most serious intraoperative and early postoperative problem. Other postoperative complications include renal dysfunction, rejection, biliary tract complications, graft vascular obstruction, and infection. With accumulating expertise in medical and surgical management and with new developments in technology (e.g., intraoperative veno-venous bypass and cyclosporine), these complications can be expected to diminish.

3. In a potential candidate for transplantation, what are the principles guiding selection of the appropriate time for surgery?

Selecting an appropriate stage for a given illness for liver transplantation is a complex isssue; transplantation just prior to death may significantly diminish the lifesaving potential of the procedure since hepatic decompensation in its latest stages poses a formidable surgical risk. Transplantation early in the course of hepatic decompensation may deprive a patient of an additional period of useful life.

An ideally timed liver transplantation procedure would be in a late enough phase of disease to offer the patient all opportunity for spontaneous stabilization or recovery, but in an early enough phase to give the surgical procedure a fair chance of success. For most patients, these phases are difficult to define prospectively.

While no single best time for surgery can be specified, transplantation should be reserved for patients in any of the following phases of disease:

- When death is imminent.
- When irreversible damage to the central nervous system is inevitable.
- When quality of life has deteriorated to unacceptable levels.

The exact choice of the time for liver transplantation in an individual requires the judgment of a qualified medical team and a well-informed patient. The following are offered as guidelines for individual liver diseases.

Extrahepatic Biliary Atresia

Biliary enteric anastomosis (hepatoportoenterostomy of Kasai) performed in the first 2 months of life provides significant improvement for at least 5 years in one-third of the patients, although cirrhosis and disappearance of the intraphepatic bile ducts occur with increasing age. While success of this procedure cannot be predicted for the individual patient, it should be used as initial therapy for extrahepatic biliary atresia. In the absence of severe hepatic decompensation in these children, liver transplantation should be delayed as long as possible to permit the child to achieve maximum growth. In children with successful hepatoportoenterostomy, liver transplantation should be deferred until progressive cholestasis, hepatocellular decompensation, or severe portal hypertension supervene.

Multiple attempts at hepatoportoenterostomy or surgical porto-systemic shunting render eventual transplant surgery technically more difficult and operationally more dangerous and therefore should be avoided in favor of liver transplantation.

Chronic Active Hepatitis

The potential for spontaneous remission and the complex course of chronic active hepatitis make valid predictions of the subsequent course difficult except in the latest stages of the disease. Using strict criteria, patients can be identified who have almost no chance of survival beyond 6 months. Such patients may be suitable candidates for transplantation.

Primary Biliary Cirrhosis

The indolent course of primary biliary cirrhosis and the potential for spontaneous improvement even in patients with advanced disease make transplantation potentially suitable only in the final stages of liver failure or when the quality of life has deteriorated to an unacceptable level.

Alpha-1-Antitrypsin Deficiency

Of the some 20 phenotypes in this genetic disorder, only Pi ZZ is associated with significant hepatic disease in children. Of infants with this phenotype, neonatal cholestasis occurs in 5.5 percent. Jaundice usually is transient, clearing before 6 months of age although biochemical evidence of activity may persist. Liver transplantation is indicated in children with Pi ZZ phenotype only when cirrhosis has developed and when evidence of hepatic failure is present.

Adults with alpha-1-antitrypsin deficiency may have liver disease associated with phenotype Pi ZZ, MZ, or SZ. If hepatic failure occurs, liver transplantation may be indicated.

Wilson's Disease

Patients with Wilson's disease usually are responsive to chelation therapy with penicillamine. However, some patients present with fulminant hepatic failure and/or progressive disease unresponsive to adequate chelation therapy. Liver transplantation may be indicated in these instances.

Crigler-Najjar Syndrome

Of the two types of this genetic disorder associated with severe unconjugated hyperbilirubinemia, patients with Type I invariably develop bilirubin encephalopathy usually before 15 months of age. Because of the inevitability of central nervous system damage and the limitations of phototherapy, liver transplantation is indicated in such patients at an early age.

Miscellaneous Metabolic Diseases

A number of rare genetic diseases may involve the liver and cause cirrhosis and eventual hepatic failure.

Patients with tyrosinemia, Byler's disease, Wolman's disease, and glycogen storage diseases Types O and IV may be candidates for hepatic transplantation.

Liver transplantation may also be indicated for patients with certain genetic diseases associated with severe neurological complications, such as hereditary deficiency of urea cycle enzymes and disorders of lactate/pyruvate or amino acid metabolism.

Hepatic Vein Thrombosis

The course of hepatic vein thrombosis is variable, and therefore transplantation should be reserved for patients with severe hepatic decompensation. The possibility of later transplant surgery should not discourage the use of portal venous decompression when otherwise indicated.

Primary Sclerosing Cholangitis

No clinical, biochemical, serologic, or histologic factors have proved to be of value in predicting outcome. When appropriate attempts at biliary tract diversion and dilatation have failed, and death from liver failure is imminent, liver transplantation should be considered.

Alcoholic Liver Disease

At least 50 percent of the cases of cirrhosis in the United States are attributable to the abuse of alcohol, and alcohol abuse is the leading cause of hepatic morbidity and mortality.

Alcoholic liver disease is most favorably affected by abstinence. The natural history of untreated alcoholic hepatitis and/or cirrhosis is extremely variable, and there are few precise prognostic indicators in any but the terminal phase of the disease.

Liver transplantation may be considered for the patients who develop evidence of progressive liver failure despite medical treatment and abstinence from alcohol.

4. What are the skills, resources, and institutional support needed for liver transplantation?

The requirements for conducting a liver transplantation program by a sponsoring institution are formidable. Accordingly, any institution embarking on this program must make a major commitment to its support. In addition to the full array of services required of a tertiary care facility and a program in graduate medical education, an active organ transplantation program should exist. Few hospitals are likely to meet these prerequisites.

Liver transplant recipients are seriously ill before surgery. The transplant effort is prodigious, and the postoperative intensive care interval, averaging 2 weeks, in punctuated by complications and frequent need for reoperation.

In this context, experts in hepatology, pediatrics infectious disease, nephrology with dialysis capability, pulmonary medicine with respiratory therapy support, pathology, immunology, and anesthesiology are needed to complement a qualified transplantation team. Extensive blood bank support to provide the needed copious quantities of blood components is mandatory. Similarly, sophisticated microbiology, clinical chemistry, and radiology assistance are required. Emotional support for patient and family warrants psychiatric participation. Availability of effective social services to assist patients and families is indispensable.

The transplantation surgeon must be trained specifically for liver grafting and must assemble and train a team to function whenever a donor organ is available. Institutional commitment to the program mandates that operating room, recovery room, laboratory, and blood bank support exist at all times. Allocation of intensive care and general surgical beds is important. Recruitment of a cohort of specialized nurses and technicians to staff these areas is necessary. Access to tissue typing capability; ongoing research programs in liver disease, organ preservation, and transplantation immunology; and available hemoperfusion and microsurgical techniques are desirable attributes of a transplantation effort.

Participation in a donor procurement program and network is essential, and an interdisciplinary deliberative body should exist to determine on an equitable basis the suitability of candidates for transplantation.

Institutions conducting liver transplantation are obligated to prospectively collect and share data in a coordinated, systematic, and comprehensive manner in all patients selected as transplantation candidates, so that the role of liver transplantation in the management of patients with liver disease can be assessed properly. Additional information permitting cost-benefit analysis should be secured.

Finally, the panel feels that adherence to these guidelines detailing the essentials to conduct a transplantation program offers the best assurance high quality in performing this very difficult operation.

5. What are the directions for future research?

The Consensus Panel identified several broad areas related to liver transplantation in which critically important information is either unavailable or so incomplete as to defy meaningful interpretation. It is recommended that a registry or clearinghouse be established for collection and evaluation of all available data on liver transplantation. Such a center would develop unified criteria for selection of patients for transplantation and for reporting and evaluating all data related to the outcome of the operation and the patients' postoperative and long-term condition. As methods of immunosuppression improve and the logistic obstacles are resolved, the feasibility and desirability of randomized clinical trials of liver transplantation should be explored for suitable subgroups of patients with specific liver diseases.

High priority also should be given to research projects related to several aspects of the transplant procedure itself. Means should be developed to improve perservation of human liver *ex vivo* and criteria should be established to evaluate its viability. Improved control of organ rejection requires urgent attention; this includes thorough evaluation of the benefits and risks of cyclosporine as an immunosuppressive agent in liver transplantation. The design of the hemodynamic support system during transplantation needs evaluation and potential improvement. Research should be encouraged for developing better supportive measures for patients in liver failure, including maintenance of proper renal and cerebral function.

In the broad areas of the cause, pathogenesis, and natural course of chronic liver disease, present knowledge is fragmentary and incomplete, and research in these areas should be fostered and supported by all available means. Particular attempts should be made to determine the possible role of liver transplantation in the management of hepatocellular carcinoma at a stage when metastatic spread appears remote. Similarly, approaches should be sought to limit infection of the transplanted liver by hepatotropic viruses. Finally, liver transplantation should be explored as a modality of replacement therapy in genetically determined multi-organ enzyme deficiencies.

Conclusion

After extensive review and consideration of all available data, this panel concludes that liver transplantation is a therapeutic modality for end-stage liver disease that deserves broader application. However, in order for liver transplantation to gain its full therapeutic potential, the indications for and results of the procedure must be the object of comprehensive, coordinated, and ongoing evaluation in the years ahead. This can best be achieved by expansion of this technology to a limited number of centers where performance of liver transplantation can be carried out under optimal conditions.

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Scurvy: A Contemporary Historical Perspective

(Third of Three Parts)

RICHARD V. LEE, M.D.

The Epidemiology of Scurvy

The epidemiology of scurvy has changed dramatically over the years and continued to change during the thirty years reviewed in this study. One aspect of its epidemiology has not changed: namely, the disease always occurs in individuals without reliable, adequate fresh food supplies. Several centuries ago sailors and soldiers and explorers often exceeded their food logistics, but as long as the crops and the weather were reliable, the agricultural world did not suffer epidemic scurvy. As cities began to expand three hundred years ago, the urban population became much like an army—at the mercy of its food supply lines. By the 19th century, scurvy had become a problem in the urban poor: the population which was most tenuously connected to their food supply. However, scurvy was not well studied by physicians at the great hospital of Europe and the British Isles, perhaps because it was not always recognized. It was not until 1883 that Barlow published his classic study of 31 children with what was described as "acute rickets" but which he recognized as scurvy superimposed upon rickets.[40] Previously, city children with cachexia and swelling of the bones were thought to have had congenital syphilis or rickets or other bone disease.

Perhaps the dramatic epidemics of scurvy in rural Ireland and Scotland following the potatoe crop failures of the 1846 and 1847 distracted medical attention from scurvy in the cities. However, there can be no illusions about the implications of Charles Dickens' mid 19th century descriptions of England's urban poor.[41]

Oslor summarized the changing epidemiology of scurvy at the end of the 19th century:[4]

> In comparison with former times it is now a rare disease. In seaport towns sailors suffering with the disease are occasionally admitted to hospitals. In large alms houses, during the winter, cases are occasionally seen.
>
> In infants and young children, fed upon improper food, a form a cachexia develops which has been regarded as acute rickets, but which Cheadle and Barlow have shown to be a form of scurvy. The most striking cases develop in infants reared on artificial food prepared with water, though the disease has occurred when these foods were prepared with milk.

The development of three important technologies contributed to the reduction of 19th century urban scurvy which preceded the elucidation of scurvy as a deficiency disease and the discovery of Vitamin C: transportation, food processing, and electrification. The effect of these three technologies was to produce a decline in the incidence of scurvy in the general population so that by WWI, the disease had again become a problem of sailors, soldiers, and prisoners. By 1950 transportation, refrigeration, and electricity made an anti-scorbutic diet available for every one, except those who refused or were unable for various reasons. The electric refrigerator and the refrigerated railroad car and truck probably did more to change the epidemiology of scurvy than did the discovery of Vitamin C.

The establishment of extensive railroads in urbanized countries allowed for the rapid transport of fresh produce into the city from the ever receding farming land. Gasoline powered trucks were able to deliver fresh foods to urban aeas distant from the rail heads. By the time of WWI most cities had road and railroad systems of provisioning their populace. The tourist attraction for the great city market place, like Covent Garden and the Haymarket, includes a sense of awe for the logistical achievement of providing fresh fruits and vegetables to a large population living at great distance from the farmer.

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The ambience of the vegetable market was admirably conveyed by Dickens' description of Covent Garden early on a London morning:

> Covent Garden market, and the avenues leading to it are thronged with carts of all sorts, sizes, and descriptions, from the heavy lumbering wagon, with its four stout horses, to the jingling costermonger's cart with its consumptive donkey. The pavement is already strewed with decayed cabbage leaves, broken hay bands, and all the indescribable litter of a vegetable market; men are shouting, carts backing, horses neighing, boys fighting, basket-women talking, piemen expatiating on the excellence of their pastry, and donkeys braying.[43]

In England one hundred years ago, cows were moved into the large towns after establishing good milking qualities. These citybound herds would be fattened for slaughter when their milk began to give out. Nineteenth century cities had neighborhood dairies and slaughter houses. Milk cows kept on the outskirts of the city would have to be milked as early as 1:30 A.M. so that their fresh milk could be delivered to the customer before breakfast. In 1865 there was a heavy mortality of city cows in London from foot-and-mouth disease and milk had to be brought to town by train.[44] As cities increased in size, the need for a safe milk supply became increasingly important. Dairy men began to take advantage of Pasteur's work in order to prevent spoilage rather than to prevent the spread of disease. By 1880 heat treated milk was being sold in Berlin and a commercial milk pastuerization plant was operating in London in 1887. New York City built a pasteurization plant in 1893. By the turn of the century, neighborhood dairies and abbatoirs were rapidly declining in number and long distance transportation of pasteurized milk was commonplace.[45]

The capability to preserve easily spoiled produce developed concomitantly with the emergence of rapid transportation. Mass production technology for canning and the development of food freezing occurred in the late 18th century.[46] Brine and cold room convection freezing methods were available for meat, fish, and poultry by 1880 and by 1905 freezing methods were established for fruits and vegetables. Quick freezing methods were developed in the 1920's and were widely adapted commercially and in the home following WWII.[47] The widespread, almost fanatic, consumption of frozen orange juice in the United States is a phenomenon of the Post WWII period, during which time childhood scurvy ceased to be a clinical problem at the Yale New Haven Hospital.

During WWI the re-emergence of scurvy among both military and civilian populations demonstrated the fragility of the food supply system and food preservation and revealed a general lack of understanding of the role of diet and disease. Fortunately, during the hostilities of the Great War, Harriette Chick and Margaret Hume at the Lister Institute of Prevention Medicine in London were defining the anti-scorbutic value of fresh and preserved foods in carefully done animal studies.[48] They were sent to Vienna in 1919 at the request of the Accessory Food Factors Committee to apply their experimental results to the problems of scurvy and rickets in the severely malnourished population of the city.[49] Twenty years later, the success of this project allowed nutritionists to guide governments and their military into workable rationing systems.

By the end of the 19th century the generation of electric power for lighting and motors was a reality. During the first half of the 20th century the distribution of electricity expanded dramatically so that by 1950 no home was involuntarily excluded from electric power. During the 1920's and 1930's reliable electric refrigeration units for the home were developed. By 1950, the capacity to store frozen and fresh fruits and vegetables was available for every household.[50]

By 1941 scurvy had ceased to be an epidemic disease because of factors unrelated to and preceding the discovery of ascorbic acid. The disease was an infrequent event in both children and adults and found only in patients with behavioral problems (mental retardation, psychiatric, feeding or alcohol related problems), underlying disease, or poverty. In contrast to the experience of 200 years ago, the afflicted patients were no longer vigorous men and women on the frontier or at war with man or nature, but young children and older adults unable to fend for themselves. During WWII scurvy was a greater problem among civilial populations and prisoner of war camps because of shortages of food stuffs than among the military combatants: prepared rations for U.S. soldiers were formulated with adequate vitamin content.

By 1950, infantile or childhood scurvy was not seen at the Yale-New Haven Hospital. Following the report of the successful treatment of infantile scurvy with ascorbic acid in 1933, the importance of ascorbic acid content of fresh fruits and vegetables was rapidly incorporated into pediatric and general practice. The chart of any pediatric inpatient at the Yale-New Haven Hospital in the 1930s, 1940s, and 1950s contained specific information about the inclusion of orange juice or citrus fruits in the diet. Since 1960, the pediatric charts have not included such specific information, in part reflecting the regular inclusion of Vitamin C in prepared infant formula and foods and the decline of scurvy as a significant pediatric problem. It is important for pediatricians to keep scurvy in mind for two reasons when dealing with mistreated children. First, the physically injured child may have a clinical presentation similar to Vitamin C deficiency. Second, mistreatment of children may include nutritional abuse so that frank scurvy may be induced in an infant fed a fad diet by misinformed adults.[51]

After 1950, scurvy was a problem confined to the lonely, demented and chronically ill: older people isolated by social or psychiatric dysfunction. The problem was neatly summarized by McMillan and Inglis in 1944:[52]

> The disease observed was typical "bachelor" scurvy. There were three root causes. First and most important was ignorance, namely in males, of the need for potatoes and vegetables in the diet. Second, was apathy leading to neglect of the same items because they require preparation in cooking. Third, was poverty, making it impossible to make an adequate diet or live anywhere but in the worst type of lodging with poor cooking facilities.

Bachelor scurvy will continue to be a problem exacerbated by increasing prices of foods, ignorance, and apathy. Fortunately, iatrogenic scurvy seems likely to decline with the recognition that severe dietary restrictions are not necessary in the management of most gastrointestinal disease, especially acid-peptic symptoms, and with the development of usable antacids and cimetadine. However, some widely used medications, prostaglandin synthesis inhibitors (aspirin, phenylbutazone) and anticonvulsants diphenylhydantoin) are known to reduce ascorbic acid levels in plasma and leukocytes and may contribute to the pathogenesis of an occasional case of scurvy.

Summary

The steady decline of scurvy as a clinical problem has been the product of both basic science research and applied technology. In fact, the major reduction in the incidence of the disease occurred during the 50 years before the discovery of ascorbic acid as a result of improved transportation and food preservation. Following the effective and widespread fortification of infant foods with vitamin C there were no infants with scurvy after 1950 at the single hospital studied. Bachelor scurvy continues to be an occasional problem. There are substantial numbers of people with marginal nutrition or iatrogenic reductions in ascorbic acid levels. These patients—food faddists, the reclusive, the elderly, the retirees and the chronically ill—have a fragile link to adequate food supplies and represent the population in which clinical scurvy will continue to develop, to the amazement of several generations of unsuspecting physicians.

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Poll Shows Preference for Limiting Hospital and Physician Payments

An "overwhelming" 81 percent of Americans over age 25 would limit hospital and physician charges to help save the financially pressed Medicare system, according to a nationwide survey released by the American Association of Retired Persons (AARP). Cost controls throughout the health care system—an all-payer system—were supported by 72 percent of those polled. That level of consensus was termed "remarkably intense and pervasive" by the pollsters, Hamilton & Staff, Inc. Fifty-nine percent of the respondents would impose direct federal or state controls on health costs, a notion that runs counter to prevailing antiregulatory sentiments.

As for other health care cost-control options, 8 percent favored raising taxes to shore up Medicare, and 5 percent suggested benefit reductions. Hospitals and physicians were seen as the chief causes of rising health care costs, with nearly three of four survey respondents saying that "excessive charges by hospitals" contribute "a great deal" to the problem and 65 percent holding the same view for physicians. AARP released the poll as it kicked off a campaign for government-controlled limits on payments for all medical services.

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Wives of COPD Patients

Cast in the Role of Caretaker

DOROTHY L. SEXTON, Ed.d., R.N.

ABSTRACT – The study was designed to determine what effect a husband's chronic obstructive pulmonary disease (COPD) has on his wife's life. The sample included 76 married women; 46 women whose husbands have a diagnosis of COPD and 30 women whose husbands do not have a chronic illness. Data were collected from the convenience sample by mailed questionnaire. Wives of COPD patients reported higher subjective stress (p = .032) and lower life satisfaction scores (p = .006) than did the comparison wives. Suggestions concerning anticipatory guidance for COPD wives are discussed.

Long-term illness is the number one health problem in the United States. Mechanic predicts that long-term care looms as "the most significant future problem in health services."[1]

One group of long-term disorders that is increasing in prevalence are the chronic obstructive pulmonary diseases. The author became aware of the predicaments experienced by men with COPD and their spouses during an earlier study[2] and through her role as a volunteer educator with the American Lung Association of Connecticut.

Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) includes those disorders characterized by increased resistance to airflow. COPD includes asthma, chronic bronchitis, emphysema and various combinations of these entities.

The COPD patient tends to have little energy available for participating in activities of daily living and is usually unable to perform customary roles. When it is the male who has COPD, it is common for the wife to help him with the treatment program, as well as to assume the role of breadwinner and to relinquish much of her own life.

According to Barstow[3] the presence of a supportive significant other person in the home is probably the single most important factor in adjustment to chronic illness such as COPD. For male patients with COPD the wife is usually the supportive person. Over time the COPD person requires more and more assistance in managing the regimen. For example, the person with COPD may depend on the spouse for transportation, obtaining prescriptions, cleaning of aerosol equipment and assisting with postural drainage including percussion. The energy expenditure, time commitment and the unpleasantness of some of these tasks may be sources of strife between the husband and wife.

The Family and Long-term Illness

A variety of functions and roles are essential to the conduct of family life and are associated with contemporary family structure. A long-term illness which affects one member of a family has implications for every other family member and demands use of a variety of adaptive mechanisms to re-establish equilibrium for the family system. During illness some roles and responsibilities of the ill family member must be assumed by others or go undone.[4] Bruhn[5] and Stevenson[6] point out that spouses often feel overburdened with their new roles and responsibilities, while the ill partner experiences a sense of loss from the change. He no longer occupies his given place in the family. There is confusion and disequilibrium for both partners. Klein, Dean and Bogdonoff[7] found that an increase in role tension, interpersonal conflict and tension was reported by both patients and spouses during illness.

The majority of individuals who have a long-term illness reside at home. Their day-to-day care is provided

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by family members. Unlike an episode of acute illness a long-term illness goes on day-after-day and, in fact, may continue for years. Therefore, no definite end can be predicted for the caretaker. In her study, Goldstein[8] found that a major problem for caretakers was role fatigue.

In spite of their pivotal role data on caretakers and their problems are sparse. No published article which addresses the issue of the impact of a husband's COPD on his wife's life was located.

Purpose

The study was designed to explore the impact of a husband's chronic illness (COPD) on the wife's life. The study was concerned with the amount of subjective stress experienced by the wives and the degree of life satisfaction. The study was also concerned with the extent to which the husbands are dependent on their wives and the problem and worries encountered on a day-to-day basis.

Method

Sample—Data were collected from a convenience sample of 76 subjects by a mailed questionnaire. Group I included 46 wives of men with a diagnosis of COPD. More than three-fourths of their husbands (N = 36, 78%) had a medical diagnosis of chronic bronchitis and emphysema, chronic bronchitis or emphysema. Of the remaining 10 husbands, four had a diagnosis of asthma and six had a diagnosis of asthma and chronic bronchitis or asthma and emphysema. Physicians rated most of the husbands as Class II (24%), III (35%) and IV (30%) which represent moderately, markedly and severely restricted activity respectively. Only three husbands were rated as Class I (recognized disease with no restrictions) and two as Class V (very severely restricted activity).

Group II consisted of 30 wives whose husbands do not have a chronic illness. The 30 women in the comparison group were recruited from church groups and social groups in the same or similar cities in which the other wives resided. This approach was used in order to obtain a comparison group with similar characteristics.

One of the COPD wives was black; all other women were white. The COPD wives and comparison women were similar on several demographic variables. They completed at least a high school education, had a family income of more than $20,000 and were retired from employment. On the average the COPD wives were 65 years of age and married for 36 years, while the comparison women had a mean age of 58 years and were married for 33 years. When the wives' ages were compared a significant difference was demonstrated ($t = -3.47$, $df = 74$, $p = .001$).

Procedure—The research proposal was approved by a Human Subject's Review Committee and by an executive group within the American Lung Association of Connecticut.

Married men with a diagnosis of COPD were identified from the rosters for patient education programs sponsored by the American Lung Association of Connecticut. The men were contacted by letter and were asked to invite their wives to participate in the study. When informed consent was received, a Verification of Illness form[9] was sent to each husband's physician to obtain a statement of diagnosis and an estimate of illness severity. The Classification of Patients with Chronic Airway Obstruction form[10] served as a guide for estimating illness severity.

The questionnaire included four sections: (1) Biographic Data form, (2) Illness Impact form,[11] (3) Subjective Stress Scale[12] and Life Satisfaction Index-A.[13]

Since the two groups of wives differed in terms of age, analysis of covariance was used to adjust the group means on these differences before comparing them on their subjective stress and life satisfaction scores.

Results

Dependence of COPD Husband on Wife—Some husbands depended upon their wives most of the time or all of the time for activities of daily living such as bathing (17%), dressing (22%), walking inside the house (13%) and cleaning aerosol equipment (13%). Three husbands depended upon their wives for these activities each day. Approximately one-half of the husbands did not require help with personal activities.

New Roles and Responsibilities—Thirty-five percent of the wives described new roles and responsibilities which they assumed because of their husband's illness. For example, wives assumed the roles of decision-maker, finance manager, errand doer and caretaker. More than one-half of the wives reported that they now took care of indoor tasks such as minor repairs, the washing of floors and windows and lifting. Sixty-one percent of the wives said that they had to assume responsibility for outdoor tasks such as shoveling snow, mowing the lawn, gardening and tending to trash removal.

Most all of the husbands needed to retire from work early without adequate preparation for it. The wives had to abruptly assume responsibilities for which they had little or no preparation. For example, the older wives had not handled the household money and few knew how to write a check. It is no wonder that many of the wives said that they felt overwhelmed and were fatigued.

Changes in Life-style—The COPD wives indicated that they gave up social activities and recreation because of their husband's illness. Nine wives reported that they and their husbands no longer bowled, went to dances or attended the theater and five said that they gave up traveling.

Some husbands were able to join their wives for occasional shopping trips. Typically the husband drove the car and the wife did the errands and carried the packages.

Ten wives emphasized the need to consider their husbands health and environment. Because his level of functioning fluctuated from day-to-day it was difficult to plan shopping trips or order theater tickets ahead of time. Several wives said that they gave up social activities because side-stream smoke tended to exacerbate their husband's symptoms.

One wife indicated that her husband depended upon her to ask others not to smoke or to put out the dining table candles. "Now he tells others that he has bronchitis, he didn't always do that."

Most wives indicated that their husbands awakened every night (40%) or some nights (54%) because of breathlessness or coughing (p = .001). Twenty-two wives reported that they tended to wake-up a few times every night and twelve said they they seldom got a good night's sleep. A few wives were sufficiently distressed that they obtained twin beds or moved to a separate bedroom.

Marital Relations—More than one-half (54%) of the wives indicated that they no longer had sexual relations. This change was apparently not viewed as negative since twenty-one reported "no desire for sexual relations" and thirteen said that "the present frequency of sexual activity was O.K."

The comparison wives described more frequent marital relations (p = .008). Only three wives said that they no longer had marital relations while four indicated no desire for sexual relations.

Wives of COPD patients may not show an interest in sexual activity because they fear precipitating an exacerbation of their husband's symptoms. Men who have COPD may not initiate sexual activity because they fear an episode of breathlessness, coughing or fatigue.

Problems and Worries—When asked what their major problems were the COPD wives indicated "his attitude, irritability and complaints" (20%), "his symptoms" (22%), "the loss of my freedom" (20%) and "the need to assume more responsibilities" (7%). The major worry identified by the wives was their husband's symptoms and condition and whether he would recover from exacerbations (44%).

Finances were also singled out as a concern by some wives. One indicated, "we pay more than $120.00 per month for medications, his lung medicines, his insulin and my heart pills." Another remarked "his illness caused us to sell our business and our home. I thought that when I retired I could enjoy our home and garden."

Because of a decrease in family income, when the husband became disabled, some wives continued working for longer years than they had planned, while others returned to work.

When problems came up the COPD wives talked with their sons or daughters (46%), with friends (35%) or with family members (26%). Only one-third of the wives shared problems with their husbands. The wives said that they feared that distressing news would cause their husbands to have a "shortness of breath attack." Some wives even expressed feelings of guilt about causing their husbands to experience breathlessness.

Close to one-third of the wives reported that their husband's COPD affected their life "a moderate amount," while ten indicated "a great deal" and ten said "slightly." Only two described the effect as "excessive" and six reported "no effect."

One wife who had to continue working described how her husband's COPD affected her life. "I have to get up at 5:00 a.m. to help my husband get washed and dressed and get a breathing treatment." Then I get his breakfast and make sure that his oxygen and medications are set for him till I return at 5:30 p.m."

The COPD wives had significantly higher subjective stress scores (p = .032) and lower life satisfaction scores (p = .006) than did the comparison wives. Analysis of covariance was used to compare the scores.

Discussion

The study was designed to determine the effect of a husband's chronic illness (COPD) on his wife's lifestyle. The results of the study indicate that COPD wives have high levels of subjective stress and low life satisfaction.

The data suggest several areas in which care givers could provide anticipatory guidance for wives whose husbands have COPD. Because of the high stress levels the wives may be vulnerable to the stress-linked disorders. Therefore, the COPD wives should be advised to have a yearly physical exam. Some wives may not tell the physician about their own symptoms because of health care costs or because they feel needed in the caretaker role.

Counseling is one avenue that would allow the wives to talk about their feelings of anger, guilt and frustration and the changes that they have had to make because of their husband's illness. Also instruction in relaxation techniques and suggestions concerning diversions would help to decrease the wives' role fatigue and lessen their levels of stress.

When the treatment plan is discussed and clarified with both the patient and the wife unnecessary problems with daily care are prevented. Also when the wife has clear information about the husband's illness, activity level and treatment plan it may help to reduce some of the stress experienced by the wife. If the wives are given instruction in pursed-lip breathing and diaphragmatic breathing and are competent in these techniques they can coach their husbands when they experience a shortness of breath episode. The wife's support is essential in helping the husband to cooperate with the treatment plan.

Husbands and wives should be counseled about the use of less stressful positions, as well as the use of relaxation techniques, bronchodilators and rest periods before starting intercourse. Couples should also be helped to explore alternative ways to express their sexuality. Other forms of expressions of love, such as caressing, holding and embracing are important for satisfaction in a relationship with another.[14]

The wives of COPD patients should be encouraged to seek help from hospital or community agencies. The Social Service Department can provide information about insurance coverage and home-care assistance. Information of this nature is particularly important when the treatment plan calls for several medications, aerosol equipment and home oxygen. The American Lung Association can supply information about educational programs, support groups, restaurants with no-smoking sections, handicap parking stickers and portable oxygen equipment.

In sum, wives whose husbands have COPD need to learn strategies for managing daily care more effectively and reducing their levels of stress. Care givers have a responsibility to help the COPD patient and wife to attain the best quality of life possible within the limits set by the chronic illness.

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The Case for Incorporating After Tefra

(First of Two Parts)

MARK E. KROPIEWNICKI, J.D., LL.M., GEOFFREY T. ANDERS, J.D., CPA, CPBC
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Changes in Federal tax laws made by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) have caused many doctors and their advisors to question the advisability of professional corporations. The best advice is clearly that each situation is unique and needs to be analyzed to determine whether to incorporate a practice in the first instance or wether to liquidate an already existing professional corporation.

This article, the first in a series of two, will enumerate and discuss the various advantages, both tax and non-tax, of the professional corporation. Part II will discuss the disadvantages of the professional corporation, the sense of incorporating a practice after TEFRA and the reasons for liquidating a presently existing professional corporation. Part II will also include worksheets to help analyze your situation and help you decide what to do.

Background

Prior to TEFRA, a doctor wanting to salt away more dollars for retirement than allowed in a Keogh plan had no choice but to incorporate and adopt qualified retirement plans. The additional benefits of using a professional corporation were mere "icing on the cake" while the detriments and extra costs of a professional corporation were easily overshadowed by the clearly tremendous benefit afforded by the retirement plans.

As most doctors are aware, TEFRA raises Keogh plan limits in 1984 to the same limits as for corporate retirement plans (annual contribution of 25% of pay up to $30,000 or the contribution needed to fund a benefit of 100% of pay or $90,000, whichever is less). In addition, doctors will now also be able to self-trustee their own Keogh plans (as is usually done by the doctors with corporate retirement plans), which was not allowed previously.

As a result of TEFRA, corporate retirement plans and Keogh plans for self-employed doctors will be essentially equal in terms of contribution levels after 1983 although there will be at least four reasons why corporate retirement plans may be preferable. First, whether through congressional oversight or deliberate intent, borrowing from a Keogh plan is not presently allowed. After some initial discussion among commentators to the contrary, it appears that no movement is afoot to change this restriction of Keogh plans. Although borrowing from a corporate retirement plan is limited (generally to the lesser of $50,000 or one-half of a participant's vested interest in the retirement plans), this ability to borrow from corporate plans is a clear advantage over Keogh plans.

Second, when staff employees leave the corporation's employ, amounts forfeited by those employees are reallocated among *all* other plan participants including the physician-employees. With a Keogh plan, the forfeitures can only be allocated to the staff employees and cannot be allocated to the owners (physicians).

Third, in some states, Keogh contributions for the self-employed doctor are not deductible for personal income tax purposes whereas contributions for a physician-employee are deductible by the corporation and not taxed to the doctor. As a result, the incorporated doctor escapes state taxation on his retirement contributions.

Finally, a distribution from a corporate retirement plan may be *totally tax-free* when made to a physician-employee who had to retire because of disability although there are conflicting tax decisions on this question and the result is not assured. Distributions to a self-employed doctor from a Keogh plan under the same circumstances will be taxed since the doctor is not an employee. Thus, use of corporate retirement plans at least give the incorporated doctor a chance at obtaining what could be a significant benefit in this situation.

Despite the above differences between corporate retirement plans and Keogh plans, they would seem unlikely to significantly sway the decision to incorporate a medical practice. Rather, retirement plans can generally be disregarded in deciding whether to incorporate or liquidate a practice. Consequently, it is necessary to determine what other tax and non-tax advantages and benefits are available to corporations; to determine the additional costs or detriments of the corporation; and to weigh the benefits against the costs in order to decide whether or not the corporate format is appropriate.

Corporate Tax Advantages

The relative value or cost of the various advantages and disadvantages of the corporation to be discussed will differ in every practice. Additionally, whether a practice is a solo physician or a group will also enter into the analysis and some of the advantages and disadvantages will apply only to solo practices, others only to group practices, while most will apply to both although perhaps to varying extents.

A corporation still offers a number of tax-free fringe benefits to its employees (including physician-employees) and various other tax advantages which are not available to unincorporated doctors.

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Health Insurance. A corporation may pay for and deduct and the physician-employee may exclude from income amounts paid by the corporation for health insurance for the physician-employee, spouse and dependents. The corporation is not required to provide equal medical insurance for all its employees. Thus, the corporation could provide more extensive medical insurance for the physician-employee while providing lesser or no medical insurance for staff-employees. Because of new limits on the deductibility of itemized medical expenses on the doctor's personal tax return, medical insurance premiums and other medical and dental expenses generally will not be deductible to the unincorporated physician.

Group-Term Life Insurance. A corporation may deduct premiums paid by it for the first $50,000 of group-term life insurance coverage for an employee, including a physician-employee, and the cost of such insurance is not taxed to the doctor. Although the corporation must also provide staff employees with some insurance, typically as a uniform percentage of salary, the cost of such coverage is minimal. If the corporation provides more than $50,000 of group-term life insurance for the doctor, the corporation still gets a deduction for the cost of the premiums but the doctor incurs taxable income in accordance with tables established by the Internal Revenue Service. If unincorporated, no deduction is allowed for any life insurance bought by the physician.

Disability Insurance. The corporation can provide disability insurance for the physician-employee and deduct the premiums which are not taxable to the doctor. However, any disability proceeds that the doctor receives from such insurance will be taxable to the doctor. Disability premiums paid by the unincorporated doctor or personally by an incorporated doctor are not deductible, however, disability benefits will not be taxed to the doctor.

Medical Expense Reimbursement Plan ("MERP"). A corporation may establish a MERP for employees to provide tax-free reimbursement of medical and dental expenses. As mentioned above, the increased floor for personal deduction of medical expenses makes it increasingly difficult for an unincorporated doctor to deduct his family's medical and dental expenses. The MERP must be non-discriminatory with respect to staff employees which tends to limit its use in many professional corporations. However, a MERP may be used in a "Cafeteria Plan" (discussed further herein) in such a way as to make the MERP more cost effective to the doctor.

Diagnostic Expense Plan ("DEP"). Similarly, a corporation may adopt a DEP to provide tax-free reimbursement of diagnostic expenses for the physician-employees of a corporation. A DEP need not include staff members but can only be used for routine "diagnostic" medical and dental visits, and for diagnostic test expenses.

$5,000 Death Benefit. A corporation may establish a tax-free $5,000 Death Benefit payable to the physician-employee's surviving spouse or estate paid on a tax deductible basis by the corporation. This benefit is only available to a self-employed physician through a Keogh plan distribution, but an incorporated doctor can take advantage of it directly from the corporation leaving retirement plan dollars to be treated in some other tax favored way.

Employee Award Program. A corporation may make tax-deductible gifts to its physician-employees (or other staff) in recognition of length of service, safety or productivity. Generally, a gift of tangible personal property valued at no more than $400 annually per physician-employee is recommended although a written non-discriminatory plan may provide for a greater employee gift. Note that the IRS disputes the tax-free treatment of these awards, so that the benefit is not assured.

Cafeteria Plan. A corporation may set up a "Cafeteria Plan" for its qualifying employees which allows each employee, doctor or staff to choose between taxable salary and a variety of other, usually non-taxable, benefits. For example, the Cafeteria Plan may provide for any or all of medical benefits (as discussed above regarding a MERP), dependent child care expenses, group-term life insurance and disability insurance. To the extent an employee does not use the Plan to pay for non-taxable fringe benefits during the year, the employee will be paid taxable cash up to the Plan's limit. On the other hand, if the employee has qualifying non-taxable expenses, they may be reimbursed to the employee tax-free. The Cafeteria Plan often allows corporate physician-employees to obtain at least a limited MERP and perhaps some of the other non-taxable benefits. If the Cafeteria Plan is established in lieu of or as part of a pay increase to the staff, for example, the corporation may obtain those same benefits for the doctor at essentially no additional cost.

Voluntary Employee Benefit Association ("VEBA"). A corporation can make tax-deductible payments to a VEBA it establishes to fund for the various above described corporate fringe benefits. Additionally, VEBAs might provide for other employee benefits such as additional insurances, separation pay, vacation home, and a variety of other possible benefits. The VEBA operates by the corporation contributing tax deductible dollars to a trust (similar to a retirement plan trust) where the contributions earn tax-free income to pay for future employee benefits.

Unfortunately, due to strict non-discrimination rules, a VEBA is probably not right for many professional corporations and many unanswered tax questions still exist concerning its use. Nonetheless, in the right situation the VEBA can be very desirable.

Educational Benefit Trust ("EBT"). A professional corporation may be allowed to currently deduct contributions made to an EBT to pay college education expenses of the physician-employee's children without currently taxing the doctor on such amounts. This result is very much uncertain at this time and there are rather stringent non-discrimination requirements. In any event, the doctor will be taxed when the EBT actually makes the payments for the education expenses of the doctor's children. This deferral of the taxation to the incorporated doctor can be a real benefit in the right situation but is unavailable to the self-employed doctor.

Fiscal vs. Calendar Year. A corporation may adopt a fiscal year other than the calendar year, while an unincorporated medical practice will rarely receive Internal Revenue Service permission to adopt a non-calendar fiscal year. Practice fiscal years other than the calendar year offer the planning possibility of choosing the tax year in which the physician will receive income and thus the possibility of deferring income and taxes.

Accumulated Earnings. Rather than the physician taking virtually all of the net earnings of the corporation out in salary, the doctor may leave some income in the corporation where it will be taxed at effective rates as low as 24% (including state tax). Subsequent earnings the corporation receives on those retained earnings will also be taxed at low rates and the corporation may invest its retained earnings in other corporation stock and exclude 85% of the dividend income it receives from tax. Accumulated dollars are eventually taken out of the corporation at capital gains tax rates when the physician retires.

Unfortunately, a professional corporation is generally limited to accumulations of only $150,000 unless the corporation has specific documented needs for accumlated earnings in excess of that amount. Also, accumulating earnings is generally not feasible or desirable in group practices and should usually be limited to use by confirmed solo practitioners. Unincorporated doctors are, of course, taxed on practice income whether or not they actually receive it, so no opportunity exists for this savings possibility.

Interest-Free Loans To Shareholders. Although the IRS continues to attack them, interest-free loans from a corporation to its shareholders can be a real benefit. The physician gets to use the loan proceeds tax-free and the corporation pays tax on the income retained to fund the loan at lower tax rates than the doctor's. However, sooner or later, the doctor will pay income tax on the loan proceeds, either when the loan is forgiven (intentionally or inadvertently) or when it is repaid to the corporation and eventually paid out to the doctor as taxable income.

Other Nondeductible Payments. If a physician has a large amount of nondeductible costs, such as payments for "goodwill" from the purchase price of another doctor's practice, incorporation is beneficial. It is less expensive for those payments to be made by corporate after-tax dollars rather than by payment of dollars taxed at the unincorporated doctor's individual tax rate, usually at or near 50%.

Non-Tax Advantages

Limited Liability. Generally, in a professional corporation, a doctor is usually only personally liable for his own malpractice or the malpractice of others he supervises. However, in an unincorporated group practice, a doctor, as a partner, can be held personally liable for the malpractice of any of his partners even if the doctor was not directly involved in that patient's care. While partners can purchase "cross-partner" liability insurance, the annual additional expense (usually 10% to 20% of each doctor's regular premium) may be far more than the ongoing extra costs of practicing in corporate form. Incorporation limits a physician's exposure for a "partner's" malpractice to his share of corporate practice assets (primarily accounts receivable) and protects his personal property.

In addition, the corporation will limit the doctor's liability for non-professional negligence or business debts of the practice. A partnership provides no such limited liability.

Better Management. The corporation format tends to force doctors into better administrative and money management routines. Corporations provide a more rigid format within which the doctors' rights and duties as owners and employees of the practice are more clearly defined than is the case in an unincorporated practice. Since it is advisable to have at least annual corporate meetings, a corporation generally provides a better management structure and a better format for getting regular input from the corporation's advisors. Even the routine of corporate minutes is useful, providing a ready reference source for previously made decisions and practice history.

Finally, many doctors find it beneficial to have the corporation regularly withhold taxes from the doctor's salary rather than having to fiddle with quarterly estimated tax payments.

Summary

Despite our attempts to derive a pure mathematical analysis to decide whether to incorporate a practice or to liquidate an existing incorporated practice, it should be evident that many of the factors which affect the decision to incorporate or liquidate a practice are not particularly susceptible to quantification. For example, the benefit to a doctor of the limited liability and management format of a corporation are virtually impossible to value for comparison purposes. Clearly those types of concerns enter into the decision making process but their desirability must be carefully weighed.

Thus far, this article has been limited to a discussion of the various advantages of the professional corporation. In Part II, we will consider the disadvantages and extra costs associated with the professional corporation, some situations where an already incorporated practice should almost surely liquidate and some situations where incorporation is preferable.

The Conscious Law

ALLEN C. GOOLSBY, III, LLB.

The doctrine of informed consent is based on the generally accepted view that every adult of sound mind has a right to determine what shall be done with his or her own body.[1] This right has been recognized in the common law as requiring a physician to obtain consent from the patient before initiating medical treatment. Such consent is not meaningful unless given intelligently. Generally, the common law doctrine requires that the physician inform the patient of all material risks of the proposed treatment and of any reasonable alternatives to the proposed course of treatment. If the physician fails to comply with the informed consent requirement, civil liability can ensue even if there is no evidence of negligence in the treatment actually rendered.

In the implementation of the common law doctrine of informed consent, there is a majority and minority view. The majority view, which is followed in Virginia, defines the duty of disclosure as that which a reasonable physician would have made under the same circumstances. In the case of *Bly v. Rhoads,*[2] the Virginia Supreme Court set forth the evidentiary requirements in an informed consent case as follows:*[The plaintiff must] show by experts that prevailing medical practice requires disclosure of certain information; that the information is material to an informed decision on treatment, and that disclosure would not pose an unreasonable threat of detriment to the patient's well being or to his ability to make a rational decision.*[2]

The minority view focuses on the reasonable patient, rather than the reasonable physician. In the primary case espousing the minority view, the court held that all material risks must be disclosed.[3] A risk was defined as material "when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."[3]

The majority view requires expert testimony to establish the prevailing medical standard. Under the minority view, no expert testimony is required, and the question of the information a reasonable patient would need to know is left to the jury. The fear that many physicians, lawyers and courts have of the minority view is that the jury will mix sympathy for the patient with hindsight as to the risks involved and find that the doctor was negligent for failing to disclose 1) a risk that is remote but may now appear to be material in light of the resulting injury, or 2) an alternative course of treatment that the physician did not consider to be a reasonable alternative for the patient. A second problem for the physician with the minority view is that the lack of reference to the prevailing medical standard leaves the physician exposed to liability without providing a means for him to ascertain in advance what must be disclosed to avoid liability.

As introduced in the 1982 General Assembly, House Bill 406 appeared to substitute the minority view on informed consent as the legal requirement for treatment of breast cancer in Virginia. In any event, if read literally, the bill would have placed an all but impossible burden on the physician. It would have required the physician to provide the patient with "*complete* and current information concerning the diagnosis and prognosis" of breast cancer in terms the patient "can be reasonably expected to understand."[4] It also would have required that "a *full,* reasonable, and comprehensible medical explanation as to the meaning, consequences and risks of the proposed course of treatment, as well as *all* alternative methods of treatment " be given to the patient by the physician prior to initiation of treatment.

Three reasons were given for the proposed legislation. The first was the fear of unauthorized mastectomies. A number of proponents of the legislation claimed that patients who have consented only to a biopsy are being put to sleep and are waking up to find that a mastectomy has been performed. The problem with this rationale is that it simply does not reflect prevailing practice. In years past, mastectomies may have been performed without consent, but the author has found no surgeon who would

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consider performing a mastectomy today on a patient who has authorized only a biopsy.

Further, under existing Virginia law there already is a remedy in the unlikely event that a mastectomy is performed where only a biopsy has been authorized. In such a case the problem is not a lack of informed consent but a lack of any consent at all. A patient treated in such a fashion would probably have a cause of action against the physician for battery as well as for violation of the common law doctrine of informed consent.

A battery is an unauthorized touching of a person. A physician who performs surgery on the body of a person commits a battery unless the surgery is done with the consent of the patient or some authorized person.[5] There is "general agreement that when a surgeon obtains consent to perform one type of procedure and subsequently performs a substantially different one, a battery has been committed, since there was no consent at all for the different procedure."[6] Therefore, "[a]n unauthorized operation is a wrongful and unlawful act for which the surgeon will be liable in damages."[6] A mastectomy which is performed after the patient has given consent only to a biopsy is unauthorized, and the physician would appear to be exposed to liability.

A physician who performed a mastectomy when only a biopsy was authorized also runs the risk of a malpractice claim under the Virginia common law doctrine of informed consent. The Virginia Code provides that the standard of care for physicians in Virginia is "that degree of skill and diligence practiced by a reasonably prudent practitioner in the field of practice or specialty in this Commonwealth."[7] I doubt that a reasonably prudent surgeon would perform a mastectomy today after receiving consent to perform only a biopsy.

A second rationale for the legislation was the continuing discovery of new data concerning breast cancer and its treatment. Recently, the public has been made aware that there are different treatments for breast cancer. The traditional radical mastectomy still is recommended by some experts, but the less invasive total mastectomy generally is considered the normal procedure today.[8] Also, other less invasive alternatives are being tried, including varying degrees of surgery, either alone or with varying amounts of radiation therapy or chemotherapy, or radiation alone.[8,9] The supporters of HB 406 intended to require physicians to discuss alternatives with their patients other than a radical or total mastectomy.

One of the principal objections to mandating such disclosure is that the effectiveness of these alternatives has not been clinically established. The less invasive procedures are being tested, but they are relatively new and long-term survival rates are needed to draw definitive conclusions.[9] While it may be appropriate to advise certain patients about less invasive alternatives, care must be taken that a patient is not misled or does not mislead herself into thinking that a non-surgical procedure may work just as well as a surgical one when it does not.

While there are early indications that procedures short of a radical or total mastectomy will produce acceptable results in certain situations, the prevailing view at the present time is that there still is not sufficient data to say with comfort that there are situations where the less invasive procedures are likely to be as successful as a total mastectomy.

It is not suggested that discussion of the less invasive alternatives is inappropriate in every case. The nature of such disclosure must depend on all of the relevant circumstances, including the physical and mental condition of the patient. But it is another matter to pressure physicians to discuss alternatives that they may consider inappropriate under the circumstances.

There can be little doubt that special breast cancer legislation will put such pressure on a physician. Even though the physician may believe disclosure of an alternative is not in the best interest of the patient, the physician's risk of exposure to a law suit has to increase if there is a statutory mandate and he or she refuses to make the disclosure.

The third argument made in support of informed consent legislation is the most disturbing one. Some proponents suggest that the consequences of a mastectomy are such that it is better to run a greater risk of death by choosing a less invasive procedure. While the suggestion that it is better to die with two breasts than to live with one may not make sense to many people, I will assume that some patients want to have this option. Even accepting this assumption, it should be obvious that it is not desirable to enact legislation that could have the effect of encouraging all patients to consider such an option.

In fact, this third argument made in support of special legislation should be considered as the strongest argument against it. The objective of any health legislation should be to improve quality of care. If special legislation will encourage consideration of less effective forms of treatment, then its contribution to quality of care will be negative rather than positive. This risk is magnified by one of the greatest misconceptions about breast cancer, namely, that each case is identical and requires the same treatment. Each patient is different. The way in which each patient reacts to treatment is different. The cancer also varies.[10] In some patients it may develop quickly, requiring more drastic treatment, while in others it develops slowly. If physicians are pressured to discuss alternatives with patients that are not feasible for that patient, there could be tragic results. In this regard, one must be concerned about encouraging unrealistic alternatives in a context where any patient naturally will have a preference for the least invasive procedure.

Another major reason for objecting to any attempt to legislate disclosure is that it puts a legislative body dangerously close to mandating one form of medical treatment over another. Obviously, a legislative body does not have the expertise to make decisions of this type. Nor, I suspect, would the average citizen believe that is it the proper province of a legislative body. A related concern is whether special legislation would set a precedent for subsequent legislation concerning other types of medical treatment. Coronary bypass operations and hysterectomies come to mind as possible examples.

Another disadvantage of special legislation is that it exposes physicians to unreasonable risks of liability. That there is uncertainty as to what should and should not be said prior to treatment for breast cancer is perhaps best evidenced by the experience in California, one of the two states that has adopted legislation relating to consent to breast cancer treatment. The California statute states, "The failure of a physician and surgeon to inform a patient by means of a standardized written summary . . . of alternative efficacious methods of treatment which may be medically viable . . . when the patient is being treated for any form of breast cancer constitutes unprofessional conduct."[11] The statute was passed in 1980 and was to have become effective on January 1, 1981. It has not yet become effective, because compiling a standardized written summary has proven impossible to date.

According to the California Medical Association, more than 25 drafts of the brochure have been prepared. The primary area of controversy has been in the tone and style of the pamphlet. There has been disagreement on the amount of weight to be given to each procedure discussed and on the option of consenting to both a biopsy and mastectomy prior to surgery.[12] The surgeons want to include the Halsted radical mastectomy as an alternative. The radiologists, on the other hand, want the Halsted method deleted and more emphasis placed on radiation therapy and chemotherapy. The plastic surgeons would like to include information on breast reconstruction. Even if all of the physicians agree, the brochure must still be acceptable to the constituency behind the legislation.[12]

If it has taken the California Department of Health Services over a year to compile a brochure, is it proper for that brochure to form the basis for liability? "Furthermore, given the rapid advance of medical science, any treatment summary will soon be outdated, at least in part."[9] The disagreement in California is confirmation that the information disclosed must be tailored to the individual patient and not legislated.

While mandating disclosure by legislation is not appropriate, education of patients and doctors is. The Medical Society of Virginia must strive to ensure that physicians in the Commonwealth are aware of current developments in the treatment of breast cancer. The Society can be especially helpful in informing physicians who do not work in large medical centers.

Where there may be uncertainty as to the effectiveness of various treatments, it is important that the physician and patient consider all reasonable treatment options. Since the physician-patient relationship is a two-way relationship, a second objective should be to provide for patient education. If the patient has background information, the quality of the discussion between physician and patient improves. With this thought in mind, the Medical Society and the Virginia Division of the American Cancer Society are joining together to produce an introductory brochure. In contrast to the situation in California, this brochure is designed to introduce the patient to the subject, rather than provide the final answer.

The patient with a diagnosis of breast cancer does have a right to know what alternative treatments may be appropriate so that she can participate intelligently in the decision as to her course of treatment. It is the physician's obligation to inform her of alternatives and the patient's obligation to learn as much as she can so that she can actively participate in the discussion. If the public discovers that physicians are as anxious to inform them about the treatment of breast cancer as the public is to know, the legitimate objective of House Bill 406 will be satisfied without the negative consequences associated with legislation.

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Month in Washington

Physician Fee Freeze Delayed by Congress

Physicians gained a temporary respite as legislators, bent on adjournment, laid aside a debate on physician fee freezes and ended the first session of the 98th Congress November 18 with the freeze and other budget items still hanging.

Fee freezes, in different forms, were attached to heavily-lobbied budget reconciliation bills neither the House nor Senate chose to grapple with in the flurry of year-end legislating.

The reprieve is likely to be short-lived, however, since reconciliation, at least theoretically, remains high on the Congressional agenda when members reconvene January 23.

In addition, some influential members in both parties want to enact deficit reduction packages that go far beyond the reconciliation measures and debate could intensify with the submission of the President's fiscal 1985 budget early in the new session. In this atmosphere, efforts to curb Medicare payments to physicians are certain to continue, and the AMA and medical specialties, having staved off a freeze in the confusing days before adjournment, are now preparing for a new battle.

In the House, debate will once again center on a Ways and Means proposal attached to the committee's budget reconciliation plan. Estimated to save $920 million over three years, the proposal would roll back and freeze limits on prevailing fees for inpatient services; mandate assignment of inpatient claims; and remove hospital staff privileges of physicians who refuse assignment.

In the Senate, physician fee debates will revolve around two different proposals—a reconciliation measure that could go to the floor at any time and a deficit reduction plan being drafted in the Senate Finance Committee.

The reconciliation measure would freeze prevailing fee limits until July 1, 1984 and would apply to outpatient as well as inpatient care. The more extensive deficit trimming proposal would continue the temporary freeze for another two years for physicians that don't accept assignment of all claims. When added to the $1.6 billion savings from the temporary freeze, the new plan would save $5.4 billion over the next four years.

The four year, $150 billion deficit reduction plan is the brain child of Finance chairman Sen. Robert Dole (R-KS). Dole pushed hard for its enactment in the last days of the session but was able in the end only to win agreement to have the staff draft a bill incorporating the major elements of his proposal as modified to suit other members. The carefully-crafted tentative compromise could unravel when talks resume in February because Sen. William Roth is threatening to offer an alternative more acceptable to the Reagan administration.

Other provisions in the tentative committee agreement include a fee schedule for clinical labs, restructuring of Medicare cost-sharing requirements, lowering the rate of increase that will be permitted in Medicare payments to hospitals, increasing Medicare Part B premiums and extending current reductions in federal payments to Medicare.

* * * * *

Federal Panel Says Abandon UCR

A federal advisory panel assigned to look at Medicare's financial problems is recommending that Medicare abandon physician payment methods in effect since the program's inception and move to regionally-adjusted fee schedules.

Since the panel is also suggesting that physicians be required to take all Medicare claims on assignment or no claims on assignment, the physician would either have to accept the Medicare fee schedule as payment in full for all his patients or he would have to bill all patients directly.

Officially known as the Social Security Advisory Council, the panel chaired by former Indiana Gov. Otis Bowen, MD, ordinarily would have looked at the entire Social Security program. Instead, this year it was instructed to concentrate on Medicare and the impending bankruptcy of the program's hospital trust fund. Its final recommendations adopted in early November are intended to generate about $300 billion to keep the hospital fund solvent through 1995.

Several other recommendations, such as the physician fee schedule and changes in the claims assignment process, would not produce savings for the hospital fund but are intended to reduce costs of the supplemental medical insurance (SMI) fund.

Prepared by the Washington, D.C.
Office of the American Medical Association

A major portion of the new revenues for the hospital fund would come from increases in federal alcohol and tobacco taxes. Other major fund raisers are recommendations to cap the amount of employer-paid health insurance premiums that are nontaxable to employees; to add a Medicare hospital surcharge to the SMI (Part B) premium; to change the way medical education is financed; and to raise the initial age of eligibility for Medicare benefits. The council rejected proposals to means test benefits or increase the payroll taxes that now fund the hospital (Part A) portion of Medicare. It also turned down a plan to use general revenues to pay for hospital care for Medicare beneficiaries.

* * * * *

Propac Commissioners Chosen

A Brandeis University dean has been chosen to head a powerful new commission expected to play a major role in updating and modifying Medicare's diagnosis-related groups (DRG) pricing scheme.

Stuart Altman, PhD, dean of the Florence Heller School at Brandeis and formerly with the Department of Health and Human Services, will serve a three-year term as chairman of the new Prospective Payment Assessment Commission (PROPAC). Among the 14 other new commission members are six physicians and four hospital officials. Many of the members have previous experience in federal or state government or advisory panels.

The commission was mandated in the law that set up the DRG system. Beginning in 1986, it is to advise HHS on needed modifications or additions in the DRGs to reflect technology and practice changes and to recommend an appropriate annual increase in the DRGs.

Among the new commission members are: John C. Nelson, MD, a practicing Salt Lake City obstetrician/gynecologist nominated by the American College of Obstetricians and Gynecologists, and Barbara J. McNeil, MD, a Harvard professor of Clinical Epidemiology and Radiology at Harvard nominated by the Society of Nuclear Medicine. Other physicians on the commission are James J. Morgan, MD, Executive Director of the Truman Medical Center in Kansas City, MO.; Yvette Francis, MD, PhD, Director of Medical Services at the Sickle Cell Center for Research in Brooklyn, N.Y.; Ernest Saward, MD, professor of social medicine at the University of Rochester Medical Center; and Steven A. Schroder, MD, professor of medicine at the University of California.

* * * * *

HCFA Sets Physician DRG Study

Health Care Financing Administration head Carolyne Davis has put together a task force of HCFA staffers to collect the Medicare Part B data that will be needed for the agency's study on the "feasibility and advisability" of including physicians in Medicare's diagnosis-related groups pricing system. The report is due in 1985. The task force is headed by Don Young, MD, Deputy Director of HCFA's Bureau of Eligibility. HCFA is developing new instructions to Medicare carriers regarding the types of data and format it wants to see. The data requested are from 1983 and HCFA wants to have it by July of 1984.

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Other Doctor Studies Also Funded

The Health Care Financing Administration will provide up to $3 million in grants in 1984 for research in several priority areas, including prospective payment and physician reimbursement. Announced in the November 9 Federal Register, grants ranging from $35,000 to $275,000 per project will be awarded for studies of: prospective payment methods for physician services; negotiated fee schedules, competitive bidding and per case payments; significant reimbursement imbalances among different physician services; ways to reduce geographic and specialty differences in reimbursement for comparable services; ways of encouraging preventive care; and changes in the claim assignment process.

* * * * *

Community Health Center Get $11 Million

Health and Human Services announced awards of $11.1 million in 62 grants to establish new community health centers or enable existing centers to open satellite clinics. The grantees are located in 32 states and territories, selected from among 191 applicants using criteria such as the medical needs of the population in the service area and the effects of unemployment on access to health care.

* * * * *

"Baby Doe" Vote Ducked by Congress

A coalition of medical and hospital groups sent letters to every member of Congress, urging him/her to delay a vote on controversial "Baby Doe" legislation. Indeed the vote was eventually postponed until at least next year as the move died with adjournment. The legislation would have permitted government intervention in the care and treatment of infants at risk with life-threatening congenital impairments. Although there have been efforts to reconcile different "Baby Doe" viewpoints, no satisfactory compromise has yet been reached. The group said Congress should hold hearings on the issue.

"Because of controversial requirements contained in this legislation, the undersigned groups are opposed to consideration of the bill at this time," it stated. The letter was signed by representatives of nine health care groups: the American Medical Association, the American Academy of Pediatrics, the American Association of Medical Colleges, the American Hospital Association, the American Psychiatric Association, the Federation of American Hospitals, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the National Association of Children's Hospitals and Related Institutions.

The bill—HR 1904, sponsored by Rep. Austin J. Murphy (D-PA)—cleared a subcommittee last March and the full Education and Labor Committee last May. Debate on the floor of the House once was scheduled for the week of Nov. 7. Now, debate may take place the next session of Congress, which starts Jan. 23.

* * * * *

Congress Tightens Fetal Research

The long debate over who should control the National Institutes of Health pursestrings was eclipsed in the closing days of Congress by a more controversial and emotional issue: fetal research.

The biomedical community watched with alarm as Rep. William Dannemeyer (R-CA), "speaking for society's unwanted members," won the majority of House votes with an amendment to the NIH bill which restricted virtually all research on fetuses intended for abortion.

The tables suddenly turned, however, when Rep. Rodney Chandler (R-WA) offered a surprise alternative: an amendment that permitted research with appropriate safeguards. Fetal research is acceptable only if it poses minimal risk to the fetus, and if scientific knowledge can be gained in no other way, the amendment said. Moreover, research would be permitted only if approved by six layers of institutional and governmental peer review, involving between 30 and 40 individuals, he added.

This more moderate amendment—along with the entire NIH bill—won the voiced support of the House, plus resounding applause. Rep. Dannemeyer, reluctant to give up, promptly asked for a count of votes, then objected to the vote, saying that a quorum was not present. Overruled, he then requested a separate vote on Chandler's amendment. Attention spans were short and legislators were eager to go home; this, too, was denied.

The medical community had two reasons to be relieved by the House vote. The moderate fetal research amendment keeps research opportunities open while making sure that safeguards are observed. The NIH bill keeps authority for NIH spending in the hands of scientists, not legislators.

The NIH bill, which reauthorizes National Cancer Institute, the National Heart, Lung and Blood Institute, and other expiring NIH programs, is a compromise between two vastly different proposals. Reps. Henry Waxman (D-CA) and John Dingell (D-MI) favored high funding levels and a line-item list of research projects specified by Congress. Reps. Richard Shelby (D-AL), James Broyhill (R-NC), and Edward Madigan (R-IL) pushed for lower funding levels and retaining the current NIH-based system of authorizing grants. The adopted compromise contains the high funding levels set in Waxman's proposal but lets NIH hand out the money.

Rep. Shelby called the NIH bill "a unified workable package that takes a consensus approach to the management of NIH." Rep. Madigan applauded the "convergence of widely divergent concerns."

A similar sense of commitment seems lacking in the Senate; these legislators have postponed consideration of their NIH bill until the next session. The legislation is believed to be accepted, although not embraced by the Reagan Administration.

* * * * *

Methaqualone Banned

The nation may follow the example of eight states in banning the controversial sedative-hypnotic drug Quaalude (methaqualone). The House of Representatives, believing the drug's danger outweighs its benefit, has voted a nationwide ban of the product. Simultaneously, manufacturer Lemmon Co. announced that it will cease production.

The states of Georgia, Illinois, Florida, Texas, Connecticut, Mississippi, New Jersey, and North Carolina already have pulled it off drugstore shelves. Prescriptions for the once-popular drug plummeted accordingly: in 1973, over 4 million prescriptions were written; by 1982, only 300,000 prescriptions were written, a reduction of more than 90%.

Distribution of existing medication in stock will stop on January 31, 1984, to give physicians and patients time to switch to other medications. The decision to discontinue the drug was due to "the increasingly adverse legislative climate that surrounds the product and the resulting negative publicity about our excellent company" said a spokesman for the drug's sole manufacturer, Lemmon Co. of Sellersville, PA.

Congress continued its push for restrictive legislation; without controls, another manufacturer might bring the drug back on the market said Rep. Henry Waxman (D-CA). The adopted bill shifts the legal status of the sedative-hypnotic from Schedule II to Schedule I, a category shared by heroin, LSD, marijuana, and other drugs for which there is no accepted medical usage. The bill was pushed by city and county physicians, who struggled to close down so-called "stress clinics"—where a person could walk off the street with a complaint of sleeplessness and get a prescription for methaqualone—as they proliferated around the country. The Food and

Drug Administration and American Medical Association opposed any change in status, saying that the drug still has accepted medical usage.

* * * * *

NIH Researchers Downplay British Pill Data

National Institutes of Health researchers are calling a new study that links oral contraceptives to cervical neoplasia "potentially important but only tentative in nature," saying that more rigorous research is needed before drawing final conclusions.

The study, published in the Oct. 22 *Lancet,* found that three forms of cervical neoplasia—invasive cancer, carcinoma-in-situ, and dysplasia—occurred more frequently in women taking the pill than in women using IUDs for birth control.

The incidence of neoplasia for women on the pills ranged from 0.9 per 1000 women-years in those with up to two years of pill use to 2.2 per 1000 women-years in those with more than eight years pill use. Women using an IUD showed no similar trend; in this group, rate of neoplasias fluctuated around 1 per 1000 women-years, reported Martin P. Vessey, MD, and colleagues at Radcliffe Infirmary, Oxford.

Based on their findings, the researchers advise that all women using the pill for more than four years seek regular cervical cytological exams. This recommendation has been endorsed by the Committee on Safety and Medicines, Britain's version of the Food and Drug Administration.

Sceptical NIH researchers point out that cervical cancer can be related to a large number of influencing factors, such as sexual behavior, cigarette smoking, and folic acid nutritional status.

NIH researchers also cautioned about a new British study linking oral contraceptives to breast cancer in young women reported in the same issue of Lancet. Recent American studies discounted the risk and in fact praised the protective effects of the pill.

At the invitation of the National Institutes of Health, British authors of the study arrived in Washington, D.C., in November, where they met behind closed doors with American researchers to exchange data, criticism and conclusions. Information obtained at the meeting will be used to form specific policy guidelines for physicians within two or three months.

The British study had found increased rates of breast cancer in young women who had taken high-progestogen forms of the pill before age 25. Breast cancer in young women, although a relatively uncommon form of the disease, tends to progress faster and be less responsive to treatment than breast cancer in older women.

Most frequently implicated were the high-progestogen combination brands of the pill: Ovulen, Demulen,Ovral, Enovid 10, Norinyl 10, Ortho-Novum 10, Lo/Ovral, Enovid 5, and Norlestrin 2-5. Risk appeared to increase with extended use; whereas relative risk was 1.0 for non-users, it climbed to 4.1 for women using the pills more than 6 years.

An editorial in the same issue of *Lancet* cautions, "The growing evidence that the pill has residual and long-term effects on health needs to be taken seriously and discussed rationally."

British researchers contend that US studies have not detected the cancer link because they focused on older patients who were unlikely to have used the pill for a long time at a young age.

But in the United States, researchers are more sceptical. This one study, while of interest, should not scare women away from the pill, say reproductive disease specialists Bruce V. Stadel, MD, MPH, and Nancy Lee, MD, of the Centers for Disease Control. The trend must first be substantiated in other studies, they say. Furthermore, they are concerned about the methodology used in the study. For example, there is insufficient information about subject characteristics, matching procedures and interviewing techniques, they say.

Moreover, American Researchers, say that they have since accumulated additional data that, when analysed, will confirm or refute the new British findings. These still-unpublished studies from CDC, NIH, Boston University, and World Health Organization contain "better numbers" than the British work, one CDC researcher confided.

* * * * *

Foreigners Competing for American Organs

On Capitol Hill there is growing concern that foreigners may overload a transplant system already stretched to capacity. More than 10,000 Americans were on waiting lists for kidney transplants last year and some 70,000 persons are on dialysis machines. However, foreigners receive between 3.5% and 7% of all American kidneys each year, according to statistics gathered by the American Society of Transplant Surgeons.

They travel from as far away as Tanzania and Qatar to take advantage of the United States' seeming endless supply of medical resources and technology. The majority are from Moslem countries where religious customs allow acceptance but not donation of organs, and less developed countries where economic constraints are the obstacle.

Payment for Physicians' Services

AMA CENTER FOR HEALTH POLICY RESEARCH

The role of third-parties in paying for physicians' services has changed greatly in the past three decades. Data from the Health Care Financing Administration indicate that third-party reimbursement accounted for 17 percent of expenditures for physicians' services in 1950. By 1981 this had grown to 62 percent. Most recently, cost containment efforts have resulted in proposed changes that may alter this trend.

Many Fortune 500 firms have initiated programs to encourage pre-paid arrangements. Sixteen states have made cutbacks in Medicaid programs by reducing or limiting physician reimbursement levels. At the national level, Congress is considering several alternative methods for reimbursing physicians. One such proposal is to freeze Medicare payments to physicians by keeping the Medicare Economic Index at its current level.

These changes will impact on the method of payment for physicians' services. This report examines two aspects of the payment issue. Specifically, these are:

- distribution of physicians' patients among third-party payors in 1983; and
- changes from 1979 to 1983 in the percentage of physicians' fees covered for a follow-up office visit.

These aspects should reflect recent changes that have occurred in the area of payment for services. Current and proposed cost-containment efforts may lower percentage reimbursements. The recent 1981-82 recession, on the other hand, would be expected to affect the level and composition of service coverage.

The data presented are from two sources: the 1983 Socioeconomic Monitoring System (SMS) Core Survey and the 1979 Periodic Survey of Physicians (PSP). For comparability, this report only uses data on office-based physicians since hospital-based physicians were not surveyed in 1979.

Distribution of Patients Among Third-Party Payors

The impact of changes in reimbursement policies on physicians will vary, depending on the relative proportion of their patients covered by third-party payors. Table 1 describes the percentage of patients principally covered by the various third-party payors for physicians' services. Approximately 77 percent of physicians' patients were covered by these payors. Of this total, 29.7 percent were publicly covered, while 47.6 percent were covered by a private payor. This implies that around 23 percent of the services received by patients were paid for out-of-pocket or by a third-party the physician was unaware of.

Data analyzed from the two surveys, but not presented in Table 1, indicate that the percentage of physicians' patients principally insured by public payors increased slightly, from 24 percent in 1979 to almost 30 percent in 1983. In 1983, approximately 21 percent were covered under Medicare and almost 9 percent under Medicaid as compared to 15.5 and 8.7 percent respectively in 1979. The observed increase in Medicare patients is consistent with an increasingly aged population.

The composition of patient coverage among third-parties varies by region and physician specialty. The West is different from other regions. Physicians in this region have 18.1 percent of their patients covered by Medicare and 9.8 percent by Medicaid, versus a national average of 20.9 and 8.8 percent, respectively. These physicians also provide services to more patients covered by pre-paid arrangements, 3.8 percent compared to 2.0 percent for all physicians, and less than 1.0 percent in the South.

The specialties most likely to be affected by reductions in the Medicare or Medicaid program are general and family practice (GP/FP) and medical specialties. On average, GP/FPs have 36 percent of their patients principally covered by these programs. On the other hand, surgical specialties rely more heavily on private payors, with only 28 percent of their patients covered by public third-party payors.

Changes in Reimbursement

Reimbursement to the physician for a follow-up office visit is an important component of an office-based physi-

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The AMA Center for Health Policy Research directs the Socioeconomic Monitoring System in cooperation with the AMA Division of Survey and Data Resources.

Table 1

PAYMENT FOR PHYSICIANS' SERVICES: PERCENT DISTRIBUTION OF PATIENTS BY PRINCIPLE-THIRD PARTY PAYORS, BY REGION AND SPECIALITY, 1983

	Public		*Private*		
	Medicare	*Medicaid*	*Blue Shield*	*Other Private*	*Pre-Pay*
ALL PHYSICIANS*	20.9%	8.8%	23.0%	22.6%	2.0%
REGION					
Northeast	20.6	8.5	26.8	18.9	2.3
North Central	23.6	8.0	23.1	21.8	2.1
South	20.9	8.9	22.2	24.4	0.9
West	18.1	9.8	21.2	23.4	3.8
SPECIALTIES					
General/Family Practice	25.4	10.6	19.0	18.0	2.6
Medical Specialties	22.3	10.2	21.3	20.0	1.7
Surgical Specialties	20.3	8.1	24.8	26.6	1.9

*Includes physicians in other specialties not reported separately.

cian's practice. Changes in these reimbursements will also affect physicians differently depending on their location and specialty. Table 2 presents the percentage reimbursement for this procedure under the Medicare and Medicaid programs and for Blue Shield plans that cover this service, for 1979 and 1983.

The results show there are gaps in the percentage reimbursements among all payors in both years. While the gap between the Medicare program and Blue Shield plans was only 4.3 percentage points in 1979, this widened by 1983. Physicians were reimbursed 68 percent of their usual fee under Medicare and approximately 77 percent under Blue Shield plans, a gap of 9 percentage points in 1983. This most likely reflects the constraint imposed by the Medicare Economic Index.

Percentage reimbursements under the Medicaid program are significantly lower than for the other two payors. This percentage equaled 53 percent of physicians' usual fees in both years. Since the reimbursement levels under Medicare and Blue Shield grew over this time period, the gap between Medicaid and these other payors widened. Average percentage reimbursements under the Medicaid program were 15 percent lower than Medicare and 24 percent lower than Blue Shield in 1983.

Analysis of the data shows that the:

- percentage reimbursements under Medicare and Blue Shield generally increased over time while those under the Medicaid program declined; and
- regional spread in percentage reimbursements for the three programs was similar by 1983.

Changes over time in these three programs vary by region. Blue Shield reimbursements increased in all regions with the greatest change, 7 precentage points, occurring in the South. Medicare reimbursements generally increased except in the West, where percentage reimbursements dropped from approximately 68 percent to 64 percent. The only region in which Medicaid reimbursements grew was in the South, increasing from 53.4 to 56.3 percent in 1983.

The regional spread in percentage reimbursements under Medicare equaled only 3.5 percentage points in 1979. By 1983, physicians in the Northeast were reimbursed 72.6 percent under Medicare versus 63.9 percent in the West, a spread of 8.7 percentage points. This differential is closer to that existing under the Medicaid and Blue Shield programs, equal to more than 10.0 percentage points in both 1979 and 1983.

Variation by specialty in percentage reimbursements, shown in Table 2, is largest within the Medicaid program. General/family practitioners were reimbursed at approximately 59 percent versus a little over 52 percent for the surgical specialties in both years. Reimbursements under Medicare and Blue Shield did not vary more than 2 percentage points among specialties in either year.

Table 2

PERCENTAGE OF FEE FOR FOLLOW-UP OFFICE VISIT COVERED BY THIRD-PARTY PAYORS, BY REGION AND PHYSICIAN SPECIALITY, 1979 AND 1983

	Percentage Fee Covered		
	Medicare	*Medicaid*	*Blue Shield*
ALL PHYSICIANS*			
1979	67.0%	53.6%	71.3%
1983	68.0	53.1	77.4
REGION			
Northeast			
1979	68.5	47.9	64.1
1983	72.6	45.2	69.9
North Central			
1979	65.9	58.5	75.6
1983	67.0	55.0	80.4
South			
1979	65.0	53.4	70.0
1983	68.5	56.3	77.1
West			
1979	68.3	55.8	76.3
1983	63.9	53.9	80.0
SPECIALTIES			
General/Family Practice			
1979	68.2	58.5	72.5
1983	70.3	58.2	77.0
Medical Specialties			
1979	68.5	53.7	70.9
1983	70.1	51.4	79.1
Surgical Specialties			
1979	68.9	51.6	72.3
1983	68.8	52.3	77.3

*Includes physicians in other specialties not reported separately.

Toxicity of Nonsteroidal Anti-Inflammatory Drugs

THE MEDICAL LETTER

The withdrawal of benoxaprofen because of hepatotoxicity (Medical Letter, 24:63, 1982) has focused attention on adverse effects of the heavily promoted nonsteroidal anti-inflammatory drugs (NSAIDs).

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

In addition to aspirin, the NSAIDs currently available in the USA are:

**Fenoprofen *(Nalfon)*
**Ibuprofen *(Motrin; Rufen)*
Indomethacin *(Indocin)*
Meclofenamate sodium *(Meclomen)*
*Mefenamic acid *(Ponstel)*
**Naproxen *(Naprosyn)*
**Naproxen sodium *(Anaprox)*
Oxyphenbutazone *(Oxalid; Tandearil)*
Phenylbutazone *(Butazolidin;* others)
Piroxicam *(Feldene)*
Sulindac *(Clinoril)*
Tolmetin *(Tolectin)*
*Zomepirac *(Zomax)*

Meclofenamate sodium, oxyphenbutazone, phenylbutazone, indomethacin, prioxicam, sulindac, and tolmetin are sold only for treatment of arthritis. Mefenamic acid and zomepirac are marketed only for analgesia (*). Ibuprofen, fenoprofen, and naproxen are approved by the US Food and Drug Administration (FDA) for both analgesia and arthritis (**). Ibuprofen, mefenamic acid, and naproxen are also promoted for treatment of dysmenorrhea.

Adverse Hepatic Effects

Benoxaprofen was taken off the market because it was associated with fatal cholestatic jaundice, especially in the elderly (BM Goudie et al, Lancet, 1:959, 1982; HM Taggart and JM Alderdice, Br Med J, 284:1372, 1982). Phenylbutazone has been associated with extensive hepatic necrosis as well as granulomatous hepatitis (SB Benjamin et al, Hepatology, 1:255, 1981). Hepatitis, sometimes cholestatic, has also been reported in patients taking sulindac, indomethacin, ibuprofen, or naproxen (AK Dhand et al, Gastroenterology, 80:585, 1981; FF Fenech et al, Br Med J, 3:155, 1967; P Sternlieb and RM Robinson, Ann Intern Med, 92:570, 1980; IP Law et al, N Engl J Med, 295:1201, 1976). Transient increases in the serum activity of the aminotransferases, especially alanine aminotransferase, may occur in the first weeks of administration; the drug should be stopped if the level of activity exceeds three times the upper level of normal. Long-term use of an NSAID may cause chronic hepatitis that improves when the drug is withdrawn.

Nephrotoxicity

All of these drugs, including aspirin, inhibit synthesis of prostaglandins that help regulate renal blood flow, glomerular filtration, and renal sodium and water excretion. NSAIDs can cause fluid retention and diminished sodium excretion, followed by prerenal azotemia, hyperkalemia, oliguria, and anuria. This type of renal toxicity is more likely in patients with renal disease, lupus erythematosus, heart failure, cirrhosis, or hypertension treated with diuretics; it can occur after only a few days of therapy and is generally reversible when the drug is stopped, but fatal hyperkalemia has been reported. A recent article described successful use of sulindac in three patients who had previously become azotemic with naproxen or ibuprofen (RD Bunning and WF Barth, JAMA, 248:2864, Dec 3, 1982), but Medical Letter consultants report that azotemia can also occur with sulindac.

In addition, acute interstital nephritis, sometimes presenting as a nephrotic syndrome, has been described in patients taking NSAIDs, particularly fenoprofen. This effect, which appears to be idiosyncratic and not related to prostaglandins, generally takes weeks or months to develop (A Finkelstein, AM J Med, 72:81, 1982; GP Chatterjee, JAMA, 246:1589, 1981). Acute papillary necrosis has occurred in patients taking these drugs, as well as in patients taking aspirin (GM Shah et al, Arthritis Rheum, 24:1208, 1981; LF Prescott, Drugs, 23:75, 1982).

Reprinted with permission from *The Medical Letter*, Vol. 25, No. 628, February 4, 1983.

Gastrointestinal Effects

All of these drugs can cause peptic ulceration. Some Medical Letter consultants are concerned that piroxicam, the newest NSAID and the one with the longest half-life, might accumulate in elderly patients and cause more gastrointestinal bleeding than other drugs in this class (Medical Letter, 24:63, 1982). Diarrhea has been associated with agents having greater enterohepatic circulation; it occurs often with use of meclofenamate sodium (SN Preston, Curr Ther Res, 23:S107, 1978).

Blood Dyscrasias

Blood dyscrasias associated with NSAIDs are rare but are among the main causes of death attributed to these drugs. All NSAIDs can interfere with platelet function and may cause bleeding in patients taking anticoagulants or those with hematological disorders. Agranulocytosis or aplastic anemia has been reported with indomethacin, ibuprofen, fenoprofen, naproxen, tolmetin, and piroxicam (A DelFavero in MNG Dukes, ed, *Side Effects of Drugs Annual 5,* 1981, New York:Excerpta Medica, p 96; SH Lee et al, Lancet, 1:1186, 1982), and there are numerous reports of blood dyscrasias with sulindac (KR Romeril et al, Lancet, 2:523, 1981; EL Morris et al, Arthritis Rheum, 24:752, 1981). Oxyphenbutazone and phenylbutazone have caused agranulocytosis and aplastic anemia, especially in the elderly, and may cause leukemia (RJ Flower et al, in AG Gilman et al, eds, *Goodman and Gilman's The Pharmacological Basis of Therapeutics,* 6th ed, New York:Macmillan, 1980, p 700).

Other Adverse Effects

NSAIDs can cause dermatitis, headaches, tinnitus, and allergic reactions. In patients sensitive to aspirin, other NSAIDs can cause bronchospasm and respiratory failure (DJ Salberg and MR Simon, Ann Allergy, 45:372, 1980; SR Ross et al, Ann Allergy, 48:233, 1982). One report suggests that tolmetin and the chemically related zomepirac may cause a higher incidence of anaphylactoid reactions than other NSAIDs (AC Rossi and DE Knapp, N Engl J Med, 307:499, Aug 19, 1982).

In patients with lupus erythematosus, aseptic meningitis has occurred with use of ibuprofen, tolmetin, or sulindac (RF Bernstein, Ann Intern Med, 92:206, 1980; GP Ruppert and WF Barth, JAMA, 245:67, 1981; ZK Ballas and ST Donta, Arch Intern Med, 142:165, 1982). Sulindac, which is structurally related to indomethacin, can cause many of the same adverse effects, including congestive heart failure, Stevens-Johnson syndrome, and toxic epidermal necrolysis; these effects also occur rarely with other NSAIDs (FDA Drug Bull, 9:29, Nov 1979; JL Miller, Ann Intern Med, 92:129, 1980). In addition, pancreatitis and a severe generalized illness with fever, rash, and lymphadenopathy (leading to one death) were recently attributed to sulindac (GD Park et al, Arch Intern Med, 142:1292, 1982; EL Lilly et al, JAMA, 246:2680, 1981; DJ Sprung, Ann Intern Med, 97:564, October 1982).

Conclusion

Nonsteroidal anti-inflammatory drugs (NSAIDs) are generally well tolerated but they can cause hepatic, renal, gastrointestinal, and hematological toxicity. Available data are not sufficient to recommend any one of these agents as safer than the others. Patients taking these drugs should probably have periodic white blood cell counts and determinations of serum creatinine concentration and hepatic enzyme activities.

NEW AMA PUBLICATION, titled Socioeconomic Characteristics of Medical Practice, contains reprints of SMS Report, the newsletter of the Association's Socioeconomic Monitoring System. The main body of the "Gray Book" is devoted to providing detailed tabulations of trends in physicians' practices, including practice activities, fees, income, and expenses. The 156-page volume also contains a comprehensive summary of information on practice characteristics in 1982 based on SMS surveys conducted throughout the past year. Copies of the book may be purchased from the AMA Order Dept. OP 165, P.O. Box 10946, Chicago, Ill. 60610. The cost is $10.80 for members or $12.00 for nonmembers, plus $3.50 shipping and handling charges.

—AMA *Newsletter,* Vol. 15, No. 39, December 14

The President's Page

The Regs Are Coming

It's frightening to read of some of the health care regulations physicians are being asked to swallow. For example, the House Ways and Means Committee recently considered a series of proposals that would have modified the Medicare program in the following respects.

1. A roll back in the Medicare prevailing charges to the level set in June 1983. This roll back would apply to physicians' services provided to hospital inpatients, and it would be effective from January 1984 to June 30, 1984.

2. Physicians would be required to accept Medicare assignment for all services provided to Medicare hospital inpatients.

3. Hospitals would be allowed to participate in the Medicare program only if all physicians on the medical staff enter into agreement to treat all Medicare inpatients on an assigned basis.

These resolutions were fortunately defeated in committee by the narrow margin of 18-15. Chairman Dan Rostenkowski D. III. however was not fazed by this setback, and was prepared to introduce these resolutions on the floor of the house with the added provision of assessing criminal penalties against physicians for failure to comply. Let me repeat, assessing criminal penalties against physicians for failure to comply. This time a narrow margin of votes again prevented the ammendments from coming to the floor and therefore effectively killed the measure for the present session. On January 23, 1984, the Congress reconvenes and these resolutions may very well come up again. Hopefully they will again be defeated, but the very fact that a respected member of the United States House of Representatives would threaten the medical profession in such a manner should give us all cause for concern.

These attempted cost-cutting regulations extend beyond federally funded patients. Third party payors are also looking for prospective payment plans and compulsory acceptance of assignment. Well financed and politically well connected, they will be petitioning the state legislature to sponsor such measures in the near future. The legal implications of such bills has already been looked into and analyzed by the AMA Department of State Legislation, with the opinion that applicable state legislation generally would not prohibit non-profit service plans from marketing contracts which would refuse payment entirely for services rendered by non-participating providers.

This in effect would contractually restrict the subscriber's freedom of choosing the source of medical care as well as the physician's freedom of choosing the method of payment. The end result will be a health care system that is the captive of public and third party payors leading to mediocrity of quality of medical care.

Physicians must therefore recognize the fact that medical politics can no longer be relegated to an extracurricular activity but must become an integral part of our daily curriculum requiring our time and money. We should support the organizations that speak on our behalf. If we don't you can be sure that no one else will.

Daniel W. Doctor, M.D.
President

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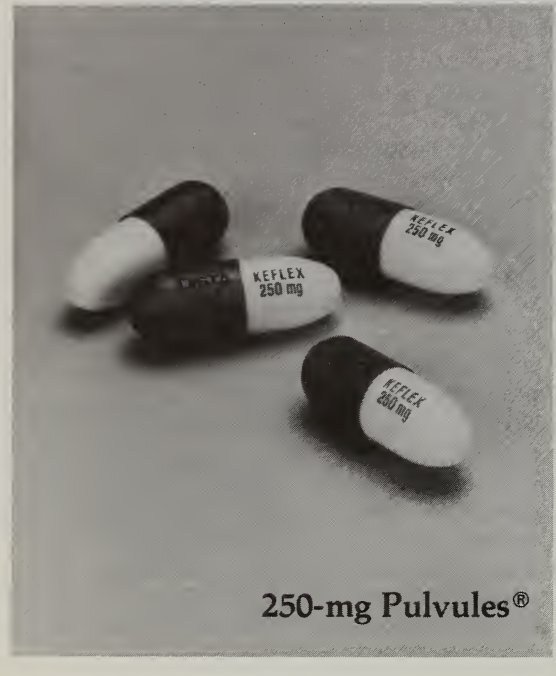

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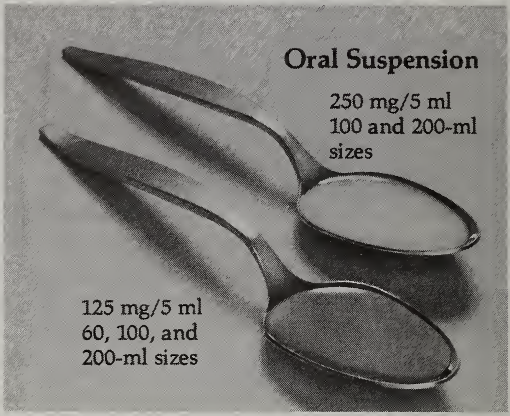

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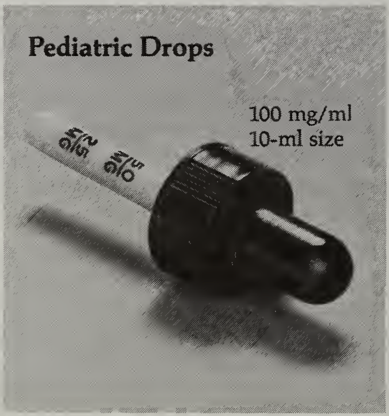

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Reflections from the Dean's Office

Surrendering Clinical Judgment

ROBERT U. MASSEY, M.D.

In a lecture to our students and faculty, a visiting professor of bioethics warned that physicians were turning their important decisions over to lawyers and accountants, giving up the ground that was uniquely theirs, setting aside their special right to make clinical judgments.

Talk of the ethics of terminating life support turns quickly to a discussion of the legal issues: let's call the attorney. And what about costs? Too much life support will surely bankrupt the family, increase the insurance rates, and ruin the hospital. No doubt that clinical judgment must include all these considerations: it concerns the life and well being of a person, it includes a whole universe:

"There is all of Africa and her prodigies in us," wrote Browne, and later, "Whilst I study to find how I am a microcosm, or little world, I find myself something more than the great."[1]

According to Hippocrates, clinical judgment is difficult. It is more than drawing decision trees or making probability guesses on a list of diagnoses and therapeutic outcomes. It is not the scientific method transposed from the laboratory to the bedside, nor is it intuition, nor remarkably keen special senses. Nor is it essentially a fine moral sensitivity coupled with whatever one learns when he is taught problem solving instead of facts. It does depend in part upon the knowledge which physicians acquire in their education and experience and which is shared by no one else. For that reason, others cannot possess it entirely; lawyers, accountants, philosophers, and patients have special knowledge which physicians may not have, but they do not have what is needed for making clinical judgments.

Mostly they do not pretend to it either. But with business coalitions telling us how hospitals should be run, with telephone hot-lines to our masters in Washington, with lawyers, accountants, regulators, and a whole host of guardians all over the place, there may be no occasion for doctors to make clinical judgments; instead they become merely skillful technicians responding to faceless controllers all acting in the public interest.

The troubling thing is that all this is happening gradually enough so that most of us hardly notice; those who speak out in warning are quickly silenced as eccentrics or troublemakers. Each age, I suspect, loses some value or ideal without anyone, except maybe the poets and some of the historians, ever taking note. The past often assumes a rosy glow, but that mostly has to do with our talent for forgetting the bad things. The ancients told of golden ages, always in the past; sometimes, as after the age of Pericles, they were right, but more often these times were only reflections out of the memories of old men.

The values and *mores* of the past slip easily from memory; it is as though we lose our receptors for certain words or concepts, cannot even recall what meanings they used to carry. We rarely speak of medicine as a *calling* in these times, and the word *vocation* has nothing like the meaning it carried only a hundred years ago. Because there are no other words for that meaning to attach itself to, the notion of being *called* to a service becomes meaningless. When physicians think of themselves as deliverers of health care, and patients are clients, then clinical judgment and ultimate concern for the patient's welfare may no longer be in anybody's mind.

There are signs that this may be turning around. Medical ethics now means something more serious than it did thirty years ago. Medical students are uncomfortable when they see us preoccupied with money; our faculty members are reaffirming their commitment to students, to their education, and to honest science. Even though values may slip away imperceptibly, some kind of early warning device gets turned on, usually in the young who, as they grow up, will almost certainly rediscover their grandfathers if we will only let them.

REFERENCES

1. Browne, Sir Thomas: Religio Medici, Part I, Sect XV; Part II, Sect XI, 1643.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut, Farmington.

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Connecticut's Informed Consent Case II

JOSEPH M. HEALEY, J.D.

In the recent case of *Logan v. Greenwich Hospital Association,*[1] the Connecticut Supreme Court was asked to consider the nature and extent of a physician's duty to advise a patient of alternatives under the doctrine of informed consent. In the *Logan* case, the trial court's jury instruction contained the following language with respect to the physician's duty to present open renal biopsy as an alternative to closed renal biopsy:

> "The theory of informed consent imposes a duty upon a doctor which is completely separate and distinct from his responsibility to skillfully diagnose and treat the patient's ills. A physician is bound to disclose all known material risks peculiar to the proposed procedure. Materiality is defined as the significance a reasonable person in what the physician knows, or should know, in his patient's position would attach to the disclosed risk or risks in deciding whether to submit or not to submit to the renal biopsy. It is the duty of the physician to give a patient whose situation otherwise permits it all information material to the decision to undergo the proposed procedure. And this duty also includes a duty of a physician to advise of feasible alternatives. Now, the duty to warn of alternatives exists only when there are feasible alternatives available. An alternative that is more hazardous is not a viable alternative. The burden is on the plaintiff to show not only an unjustified failure to discolse the risk of a proposed procedure, but also that such failure was the proximate cause of the plaintiff's injury."[2]

The plaintiff objected to one sentence in this charge, that which characterized a more hazardous alternative as not a viable alternative and, therefore, as one which need not be disclosed. The plaintiff contended that this interfered with the patient's right to sufficient information as the basis for the exercise of informed consent. The Connecticut Supreme Court agreed, finding error in the jury instruction and ordering a new trial limited to consideration of the failure to obtain informed consent alleged by the patient.

The Court's decision was based in part on its concern that such an instruction was in conflict with the patient's right to consent:

> "The instruction that an alternative which is more hazardous is not viable and, therefore, need not be mentioned to the patient has the effect of limiting the physician's duty to disclosure of only the least hazardous procedure available, presumably the one contemplated. The issue then becomes, not whether the patient has been informed of viable alternatives, but whether the doctor has recommended the least dangerous of them, because those which are more hazardous need not be discussed. This instruction, therefore, wholly relieves physicians of any obligation to discuss alternatives with their patients and substitutes merely a duty to recommend the safest procedure. It is incompatible, therefore, with the view which the trial court expressed in the remainder of the charge that the patient must be provided with sufficient information to allow him to make an intelligent choice."[3]

The Court's decision was also based in part on its concern about the effect of the instruction upon the jury:

> "The major focus of the testimony on the issue of informed consent was the relative hazard involved in each of the two medical procedures. In advising the jury that more hazardous alternatives were not viable and could be withheld from the patient, the trial court invited them to decide the issue of informed consent simply by comparing the risks of the two procedures. The jury could well have understood that, if they concluded that an open biopsy was more hazardous than the needle biopsy performed, there was no duty to inform the plaintiff of that alternative. Such a misunderstanding would have been wholly inconsistent with the view we have adopted requiring that all viable alternatives be disclosed even though some involve more hazard than others."[4]

The result of the Court's decision was not a judgment that the physician was liable for failure to obtain informed consent in this case. Rather the result was that there should be a new trial of the informed consent issue applying the standards clarified by the Supreme Court.

Discussion of the implications of the case will continue next month.

REFERENCES

1. 191 Conn 282 (1983).
2. Id at 287.
3. Id at 294
4. Id at 295

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

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SUMMARY OF PROCEEDINGS
HOUSE OF DELEGATES–SEMI–ANNUAL MEETING
Ramada Inn, North Haven–November 17, 1983

Reports and Resolutions

The House of Delegates received reports from the President, the Council, the AMA Delegation, William Whalen, M.D., President of Connecticut Peer Review Organization (CPRO), and Tim Norbeck, Executive Director. Resolutions were also received from the Council and individual members.

Principal Actions Taken

(a) **Report of the President,** Daniel W. Doctor, M.D., Westport: The House VOTED to accept the report of the President which highlighted his attendance at the interim meetings of the county medical associations and his efforts in promoting CSMS and AMA membership. Dr. Doctor also reported on federal legislation regarding the Medicare Program. Elements of the proposed legislation would have imposed a freezee on physician's fees and required mandatory assignment for in-hospital Medicare patients. The measures were to be voted on after the Thanksgiving recess of the Congress.

(b) **Report of the Council,** Guy W. Van Syckle, M.D., Danbury, Chairman of the Council: The House VOTED to accept the report of the Chairman of the Council, which reviewed the activities of the Council since the past meeting of the House of Delegates. Special emphasis was placed on the Professional Liability Program, the Connecticut Peer Review Organization, activities of the AMA Health Policy Task Force and the budget. (The complete report is published elsewhere in this issue of *Connecticut Medicine.*)

(c) **Report of the AMA Delegation:** The House VOTED to accept and approve the report of the AMA Delegation which was prepared by Orvan W. Hess, M.D. The comprehensive report contained all of the principal actions taken at the 1983 Annual Meeting of the AMA House of Delegates.

Dr. Hess noted that the forthcoming meeting of the AMA would be his last as a delegate from the Connecticut State Medical Society and thanked the CSMS House of Delegates for allowing him the opportunity to serve the Society as a delegate. Members of the House rose in unison and accorded Dr. Hess a standing ovation.

(d) **Other Reports:**
CPRO Update—William A. Whalen, M.D., Willimantic, President of the Connecticut Peer Review Organization, provided members with a concise progress report of the activities of that agency. He indicated that Ms. Marcia Petrillo, currently Executive Director of the Hartford County Health Care Plan, had been employed as the Executive Director of CPRO and that a Search Committee had been established to seek a Medical Director.

Dr. Whalen reported that PSRO's had received funding from Washington until December, 1983 and that the HCHCP had voted to support CPRO needs on an interim basis. He noted that the Board of Directors of CPRO had approved the business proposal which subsequently was submitted to the Fairfield Westchester Business Group on Health, Blue Cross-Blue Shield of CT, and Connecticut General.

Representatives of CPRO and the Connecticut Hospital Association are working cooperatively on the development of the CPRO/Hospital Agreement according to Dr. Whalen. He concluded his remarks by noting that formal invitations for CPRO membership will be mailed in November.

Timothy B. Norbeck, Executive Director, who serves on the Advisory Committee to the AMA Executive Vice President, reported on the meeting which he had attended in Chicago on the previous day. He mentioned in detail HR 4170, the Medicare proposal which would impose a freeze on physician fees and require physicians to accept assignment on all in-patient Medicare hospital patients. Mr. Norbeck reported that the measures were going to be difficult to defeat and that the votes would be close. He also mentioned the Equitable Life Assurance Society survey conducted by Louis Harris and Associates and stated that many of its results seemed to be in conflict with a recent AMA survey.

(e) **Budget for 1984:** The House VOTED to approve the budget for 1984, as prepared and recommended by the Council, with the addition of $1000 each to the line items of the Student and Resident Sections. The House also VOTED to accept a $25 dues increase so that membership dues will be $175 in 1984.

The House VOTED to adopt the following resolutions:

Resolution on Payment for Physicians' Services

RESOLVED: That the CSMS favors the principle of indemnity payment because it maintains and preserves the basic and traditional relationship between physician and patient and separates that relationship from the third party payors, and, be it further

RESOLVED: That the CSMS House of Delegates urge the AMA House of Delegates to take the necessary steps to implement this policy.

Resolution on Insanity as a Legal Defense

RESOLVED: That the CSMS urge the AMA to undertake collaborative efforts with the American Bar Association and the American Psychiatric Association to achieve a common policy position concerning the insanity defense and; be it further

RESOLVED: That the AMA Board of Trustees report any progress made in such efforts in a timely fashion to the AMA House of Delegates.

Resolution on Honorary Degree of Doctor of Medicine introduced by New Haven County Medical Association

WHEREAS: The New Haven County Medical Association will celebrate its Bicentennial in 1984: and

WHEREAS: Mr. Norman Cousins will address the Bicentennial convocation on the progress and current state of medical care; and

WHEREAS: Mr. Cousins is a distinguished literary figure and a teacher of the humanities to medical students and physicians; and

WHEREAS: Mr. Cousins' efforts have benefited the welfare of the people of the State of Connecticut: therefore be it

RESOLVED: That the Connecticut State Medical Society confer upon Mr. Norman Cousins the honorary degree of Doctor of Medicine.

The following resolution was referred to the Council for consideration:

Resolution on Organ Transplantation

RESOLVED: That the House of Delegates of the CSMS declare that liver transplantation to be an accepted therapeutic procedure and recommend that all third party payors in Connecticut recognize liver transplantations as a reimbursable surgical procedure.

CSMS Past Service Awards to Officers and County Councilors

OFFICERS

Joseph S. Sadowski, M.D., Hartford Vice Speaker-Speaker CSMS House of Delegates	1979-1983
Edmund F. Hecklau, M.D., Greenwich Vice Speaker-Speaker CSMS House of Delegates	1980-1983
Orvan W. Hess, M.D., North Haven Alternate Delegate-Delegate American Medical Association	1969-1983
Andrew J. Canzonetti, M.D., New Britain Councilor-at-Large	1982-1983

COUNTY COUNCILORS

Hartford	
Merrill B. Rubinow, M.D., Manchester Councilor	1979-1983
Lawrence B. Ahrens, M.D., New Britain Associate Councilor	1982-1983
New London	
Frederick C. Barrett, M.D., Norwich Associate Councilor Councilor	1973-1983
Windham	
John R. Hayes, M.D., Willimantic Associate Councilor Councilor	1981-1983

Council Meeting

Thursday, November 17, 1983
Ramada Inn, North Haven, Connecticut

Attendance

Present were Drs. Doctor, Whalen, Sadowski, Zlotsky, Mendillo, Ahrens, Parrella, Hess, Van Syckle, James, Abbot, Freedman, Petrie, Orphanos, Kaess, Eslami, Bobruff, Villa, Waldron, Ragusa, Sullivan, Alisberg, McDonnell, Czarsty, and Ahamed.

Also present: Mr. Norbeck, Mrs. Lindquist and Theodore Zanker, Pres. NHCMA.

Absent were: Drs. Friedberg, Canzonetti, Beck, Concannon, Reyelt, Sharon and Leach.

Resolution on Honorary Degree

Dr. Guy W. Van Syckle, Chairman of the Council, called a meeting of the Council during an intermission of the House of Delegates meeting for the purpose of hearing a resolution from the New Haven County Medical Association concerning the awarding of an Honorary Degree of Doctor of Medicine during their bicentennial year in 1984. According to the CSMS Bylaws, "The Council may recommend to the House of Delegates the bestowal of an Honorary Degree in Medicine upon any person not a physician, distinguished in the sciences of medicine or for contribution to human welfare." Since New Haven County Medical Association wished to have this "Honorary Degree" given prior to the next Annual Meeting of the House of Delegates, the Chairman of the Council called the meeting of the Council in order that New Haven County's resolution could be acted upon immediately.

Dr. Eslami, Councilor from New Haven County, introduced the following resolution:

Resolution

SUBJECT:

HONORARY DEGREE OF DOCTOR OF MEDICINE NEW HAVEN COUNTY MEDICAL ASSOCIATION BICENTENNIAL

WHEREAS: The New Haven County Medical Association will celebrate its Bicentennial in 1984; and

WHEREAS: Mr. Norman Cousins will address the Bicentennial convocation on the progress and current state of medical care; and

WHEREAS: Mr. Cousins is a distinguished literary figure and a teacher of the humanities to medical students and physicians: and

WHEREAS: Mr. Cousins' efforts have benefited the welfare of the people of the State of Connecticut; therefore be it

RESOLVED: That the Connecticut State Medical Society confer upon Mr. Norman Cousins the honorary degree of Doctor of Medicine.

Following discussion, it was VOTED to approve the resolution and to recommend its approval to the House of Delegates.

The meeting adjourned with no other action being taken.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on November 17, 1983. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

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CONNECTICUT STATE MEDICAL SOCIETY 1983 SEMI-ANNUAL MEETING HIGHLIGHTS

Keynote speaker Grant V. Rodkey, M.D., Massachusetts, Council on Medical Service of the AMA, offers comments regarding trends in physician reimbursement systems.

Daniel W. Doctor, M.D., CSMS President Presents Service Awards

Joseph S. Sadowski, M.D., Hartford, right, accepts service award for his years as Speaker of the House of Delegates prior to his election as CSMS Vice-President in May.

Edmund H. Hecklau, M.D., Greenwich, left, receives service award for his years as Vice-Speaker of the House of Delegates.

Frederick C. Barrett, M.D., Norwich, right, accepts citation for his years of service as Councilor to the Society from New London County Medical Association.

Orvan W. Hess, M.D., New Haven, left, receives service award for long and distinguished service to the Society as Delegate to the AMA.

References:
1. Stone PH, Turi ZG, Muller JE: Efficacy of nifedipine therapy for refractory angina pectoris. *Am Heart J* 104:672-681, September 1982.
2. Antman E, Muller J, Goldberg S, et al: Nifedipine therapy for coronary-artery spasm: Experience in 127 patients. *N Engl J Med* 302:1269-1273, June 5, 1980.

BRIEF SUMMARY
PROCARDIA® (nifedipine) **CAPSULES** For Oral Use

INDICATIONS AND USAGE: I. Vasospastic Angina: PROCARDIA (nifedipine) is indicated for the management of vasospastic angina confirmed by any of the following criteria: 1) classical pattern of angina at rest accompanied by ST segment elevation, 2) angina or coronary artery spasm provoked by ergonovine, or 3) angiographically demonstrated coronary artery spasm. In those patients who have had angiography, the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina, provided that the above criteria are satisfied. PROCARDIA may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed, e.g., where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm, or when angina is refractory to nitrates and/or adequate doses of beta blockers.

II. Chronic Stable Angina (Classical Effort-Associated Angina): PROCARDIA is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents.

In chronic stable angina (effort-associated angina) PROGARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in those patients are incomplete.

Controlled studies in small numbers of patients suggest concomitant use of PROCARDIA and beta blocking agents may be beneficial in patients with chronic stable angina, but available information is not sufficient to predict with confidence the effects of concurrent treatment, especially in patients with compromised left ventricular function or cardiac conduction abnormalities. When introducing such concomitant therapy, care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs. (See Warnings.)

CONTRAINDICATIONS: Known hypersensitivity reaction to PROCARDIA.

WARNINGS: Excessive Hypotension: Although in most patients, the hypotensive effect of PROCARDIA is modest and well tolerated, occasional patients have had excessive and poorly tolerated hypotension. These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment, and may be more likely in patients on concomitant beta blockers

Severe hypotension and or increased fluid volume requirements have been reported in patients receiving PROCARDIA together with a beta blocking agent who underwent coronary artery bypass surgery using high dose fentanyl anesthesia. The interaction with high dose fentanyl appears to be due to the combination of PROCARDIA and a beta blocker, but the possibility that it may occur with PROCARDIA alone, with low doses of fentanyl, in other surgical procedures, or with other narcotic analgesics cannot be ruled out. In PROCARDIA treated patients where surgery using high dose fentanyl anesthesia is contemplated, the physician should be aware of these potential problems and, if the patient's condition permits, sufficient time (at least 36 hours) should be allowed for PROCARDIA to be washed out of the body prior to surgery.

Increased Angina: Occasional patients have developed well documented increased frequency, duration or severity of angina on starting PROCARDIA or at the time of dosage increases. The mechanism of this response is not established but could result from decreased coronary perfusion associated with decreased diastolic pressure with increased heart rate, or from increased demand resulting from increased heart rate alone.

Beta Blocker Withdrawal: Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina, probably related to increased sensitivity to catecholamines. Initiation of PROCARDIA treatment will not prevent this occurrence and might be expected to exacerbate it by provoking reflex catecholamine release. There have been occasional reports of increased angina in a setting of beta blocker withdrawal and PROCARDIA initiation. It is important to taper beta blockers if possible, rather than stopping them abruptly before beginning PROCARDIA.

Congestive Heart Failure: Rarely, patients, usually receiving a beta blocker, have developed heart failure after beginning PROCARDIA. Patients with tight aortic stenosis may be at greater risk for such an event.

PRECAUTIONS: General: Hypotension: Because PROCARDIA decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of PROCARDIA is suggested. Close observation is especially recommended for patients already taking medications that are known to lower blood pressure. (See Warnings.)

Peripheral edema: Mild to moderate peripheral edema, typically associated with arterial vasodilation and not due to left ventricular dysfunction, occurs in about one in ten patients treated with PROCARDIA. This edema occurs primarily in the lower extremities and usually responds to diuretic therapy. With patients whose angina is complicated by congestive heart failure, care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

Drug interactions: Beta-adrenergic blocking agents: (See Indications and Warnings.) Experience in over 1400 patients in a non-comparative clinical trial has shown that concomitant administration of PROCARDIA and beta-blocking agents is usually well tolerated, but there have been occasional literature reports suggesting that the combination may increase the likelihood of congestive heart failure, severe hypotension or exacerbation of angina.

Long-acting nitrates: PROCARDIA may be safely co-administered with nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

Digitalis: Administration of PROCARDIA with digoxin increased digoxin levels in nine of twelve normal volunteers. The average increase was 45%. Another investigator found no increase in digoxin levels in thirteen patients with coronary artery disease. In an uncontrolled study of over two hundred patients with congestive heart failure during which digoxin blood levels were not measured, digitalis toxicity was not observed. Since there have been isolated reports of patients with elevated digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing PROCARDIA to avoid possible over- or under-digitalization.

Carcinogenesis, mutagenesis, impairment of fertility: When given to rats prior to mating, nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose.

Pregnancy: Category C. Please see full prescribing information with reference to teratogenicity in rats, embryotoxicity in rats, mice and rabbits, and abnormalities in monkeys.

ADVERSE REACTIONS: The most common adverse events include dizziness or light-headedness, peripheral edema, nausea, weakness, headache and flushing each occurring in about 10% of patients, transient hypotension in about 5%, palpitation in about 2% and syncope in about 0.5%. Syncopal episodes did not recur with reduction in the dose of PROCARDIA or concomitant antianginal medication Additionally, the following have been reported: muscle cramps, nervousness, dyspnea, nasal and chest congestion, diarrhea, constipation, inflammation, joint stiffness, shakiness, sleep disturbances, blurred vision, difficulties in balance, dermatitis, pruritus, urticaria, fever, sweating, chills, and sexual difficulties. Very rarely, introduction of PROCARDIA therapy was associated with an increase in anginal pain, possibly due to associated hypotension.

In addition, more serious adverse events were observed, not readily distinguishable from the natural history of the disease in these patients. It remains possible, however, that some or many of these events were drug related. Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2%. Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0.5% of patients.

Laboratory Tests: Rare, mild to moderate, transient elevations of enzymes such as alkaline phosphatase, CPK, LDH, SGOT, and SGPT have been noted, and a single incident of significantly elevated transaminases and alkaline phosphatase was seen in a patient with a history of gall bladder disease after about eleven months of nifedipine therapy. The relationship to PROCARDIA therapy is uncertain. These laboratory abnormalities have rarely been associated with clinical symptoms. Cholestasis, possibly due to PROCARDIA therapy, has been reported twice in the extensive world literature.

HOW SUPPLIED: Each orange, soft gelatin PROCARDIA CAPSULE contains 10 mg of nifedipine. PROCARDIA CAPSULES are supplied in bottles of 100 (NDC 0069-2600-66), 300 (NDC 0069-2600-72), and unit dose (10x10) (NDC 0069-2600-41). The capsules should be protected from light and moisture and stored at controlled room temperature 59° to 77°F (15° to 25°C) in the manufacturer's original container.

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SEMI-ANNUAL REPORTS TO THE HOUSE OF DELEGATES OF THE CONNECTICUT STATE MEDICAL SOCIETY

November 17, 1983

Report of the Council

GUY W. VAN SYCKLE, M.D., CHAIRMAN

The Council has met three times since the Annual Meeting of the House of Delegates held May 25, 1983. All members of the House have received detailed copies of the minutes of each meeting. This report is limited to those matters which are felt to merit special emphasis.

1. Professional Liability Program

The CSMS and County sponsored CNA plan's rate increases average approximately 14% for physicians and 17% for surgeons. The Aetna rates, which already start at a higher level have increased approximately 13% for physicians and approximately 20% for surgeons. The CNA classification of both ophthalmologists and urologists have been lowered to levels competitive with Aetna.

The CNA Insurance Company in conjunction with the CNA Advisory Panel is presently developing a Loss Control Program which will be available to the CNA insured in the Fall of 1983. The format will be a day long seminar, incorporating video tapes and discussion. Once this program is completed and approved by CNA, we anticipate granting a premium credit of up to 5% to those physicians and surgeons attending these programs. Both St. Paul and Aetna continue to offer their claims made policies with St. Paul maintaining a price advantage in most categories but for somewhat lower limits.

The Council and CSMS continue to monitor the professional liability climate in our State through reports from CNA, company rate filings and through services of independent actuarial and insurance consultants retained by CSMS on a permanent basis. The Committee on Professional Liability and Council have heard two recent proposals for more effective and innovative methods of funding professional liability and are actively investigating these further. We were successful in the Legislature this year in defeating legislative attempts to extend the present three-year Statute of Limitations to an indefinite period. In addition, we were able to persuade the Legislature to extend the Charter of the CSMS captive insurance company for an additional two years in the event the market climate detoriorates in the near future.

2. Reports from Physicians and Staff Regarding Activities of State and Federal Agencies

The Council has continued to receive on-going reports concerning the delineation of House and Senate initiatives in health care cost containment and, in particular, the prospective payment system under Medicare, which went into effect as of October 1, 1983. The landmark program was enacted as part of the Social Security Amendments of 1983 (P.L. 98-21) and set out the mechanisms for establishing reimbursement levels for 467 diagnostic related groups (DRGs). The program, to be phased in over three years and finally based on a national payment rate, will be based on a blend of the cost-based hospital-specific rates and the regional/national DRG rates. Additional payments are authorized for lengthy or very costly treatments (Outliers) as compared to the norm for a specific diagnosis. Exempt from the system are childrens, psychiatric, rehabilitation and long term hospitals which will continue to be made on a reasonable cost basis.

Discussions have been held by the House Ways and Means Committee concerning a proposal to freeze physicians' fees for a period of six months at the prevailing rate and mandate assignment for all inpatient hospital services. The supporters of the freeze/assignment proposal believe mandatory assignment will work in future years as the physician surplus increases. Proposals of this nature indicate that Congress views control of physicians' fees as essential in its attempts at reducing the ever-increasing cost of Medicare. As a part of the Social Security Amendments, Congress required Health and Human Services to study the feasibility of including physicians' fees in the prospective payment system. That report is due in 1984 and is expected to kick-off a lengthy Congressional debate over physician-reimbursement.

In other federal action, the Reagan administration has eased its adversarial position regarding funding on both the health planning program and the Peer Review Systems Organization. They have signed a continuing resolution which authorized federal support and assures their continuation.

The National Health Planning Program reauthorization has been supported by a new compromise effort offered by Representative Madigan, which has the support of the Reagan administration. This continues the current program while raising the Certificate of Need (CON) threshold and giving states more options in administration. The present planning program could be replaced by an optional health resources review program. States would have an option to participate and to continue HSA's in its review process. The CON threshold would be increased from our current levels of $600,000 for capital expenditures, $400,000 for major medical equipment and $250,000 for institutional services to $5,000,000 for capital expenditures, $2,000,000 for major medical equipment and $1,000,000 for institutional services. States that now have lower CON thresholds could retain lower thresholds if they could demonstrate that they had adequate resources to conduct more extensive reviews. Representative Madigan's proposal does not apply to physicians' offices.

3. Peer Review Organization

The Connecticut Peer Review Organization was incorporated in August of 1983 and its first Board meeting held August 18, 1983. The following officers were elected: William A. Whalen, Jr., M.D., President; William A. Schear, M.D., Vice-President; Mr. Carl Lindquist, Secretary; and Joseph Camilleri, M.D., Treasurer. In addition, elected to the Executive Committee were Andrew J. Canzonetti, M.D. and Neil A. Dreyer, M.D. The Acting Medical Director was Joseph Camilleri, M.D. and the Associate Acting Director, Benjamin Wiesel, M.D. Mrs. Marcia Petrillo presently Executive Director of the Hartford County Health Care Plan was elected as the Executive Director. A Search Committee, consisting of Doctors Whalen, Dreyer and Mr. C. Lindquist, are seeking a full-time Medical Director to begin duties by January of 1984. Funding of the new organization continues to be a major concern. At present, the PSROs are being provided funds for October and November, but November funding has conditions based on whether Congress appropriates funds for the new fiscal year. An amendment to the Administration's budget in the House of Representatives adds $9,000,000 for PSRO transitional funding. This is favorable for use in proposed HCHCP contributions to the CPRO for the next three months.

4. American Medical Association

Frank Abbot, M.D., and Stewart Petrie, M.D. have attended initial meetings of the AMA Health Policy Task Force and the AMA Health Policy Agenda respectively.

Robert McAfee, M.D., AMA Delegate from Maine and presently Chairman of the Long Range Planning Committee of the AMA has announced his candidacy for the AMA Board of Trustees in June of 1984. Doctor McAfee is an outstanding candidate for this position and well known to the Connecticut Delegation. He will be running as a candidate from New England. His qualifications were discussed at the Council meeting and it was voted to contribute $5,000 to Doctor McAfee's campaign for elective office and to transmit this action to the House of Delegates for approval.

At the last AMA meeting, Report D of the Council on Medical Service regarding Payment for Physicians' Services was submitted to the House of Delegates. The report recommended that serious consideration be given by all third party payers to changing the present system of payment based on "Usual, Customary and Reasonable" (UCR) to a payment system based on indemnity principles. The AMA Council on Medical Service recommended that members of the House consider the matter of physician reimbursement by means of indemnity versus UCR with their constituents and other concerned parties over the next six months, communicate any additional views and comments to the AMA Council and come to the next interim meeting of the Association prepared to further express their views on the subject. The CSMS Council and AMA Delegation has had this subject under consideration and at the October 26 meeting, a resolution recommending that CSMS approve the principle of changing UCR basis of physician reimbursement to an indemnity basis was discussed. It was voted to approve the resolution and transmit it to the House of Delegates for approval. Attached to the resolution is a synopsis of the AMA Council on Medical Service report.

5. 1984 Budget

The budget was reviewed line by line by the Treasurer and after several amendments were made, the Council voted to approve the budget and transmit it to the House of Delegates with the Council's recommendation that the dues structure of $175 (an increase of $25) and budget be approved by the House.

6. Conclusion

As indicated in the opening paragraph, only matters that are thought to be of major importance were included in this report. The members of the House are urged to review the minutes of the meetings held since the Annual Meeting of the House of Delegates. As Chairman of the Council, I will be very happy to answer any questions about any items in this report or about any other items recorded in the minutes of the Council. At this time, the Chairman would like to express his appreciation and thanks to all members of the Council and staff whose cooperation and assistance have been invaluable.

Connecticut State Medical Society

1984 BUDGET

The House of Delegates approved the 1984 Budget and membership dues for 1984 are set at $175.00

Income:

Estimated Income from Dues (@ $175.00)	$700,000
Estimated Income from Journal	50,000
Building Income	8,000
Interest & Dividends	50,000
Reimbursement, Collection of AMA Dues	4,500
Miscellaneous Income	1,000
	$813,500

Budget Allotments:

General

President of the Society (Honorarium)		$ 1,750	
Chairman of the Council (Honorarium)		1,250	
Council Expense		4,000	
Delegates to AMA (8 Del., Pres., Pres-Elect)		27,600	
Travel	$10,000		
Lodging	9,000		
Per Diem	3,600		
N.E. Hospitality Suite (AMA Mtgs)	5,000		
(Mtgs. Chicago & Honolulu)	$27,600		
Legal Counseling		7,000	
Legislative Counseling		15,000	
Legislative Activities		8,000	
Employees' Pension Fund		42,000	
Trustees' Administrators' Fees-Pension Fund		2,500	
Premiums for Employees' Health Insurance Plans		17,000	
Reserve for Contingencies		50,000	
Annual & Semi-Annual Meetings		13,000	
General Insurance		3,000	
Public Information Program		12,000	
FTC Complaint, CSMS-NHCMA Defense		–	
David A. Grendon Memorial Fin. Aid Fund of CSMS		8,000	
Committee Allotments, Dues, Etc.		17,925	
Public Health	400		
Legislation	500		
Liaison Comm. Pharm. Assoc.	250		
Cancer Coordinating Committee	300		
Mental Health	100		
Hospital Committee	100		
Third Party Payments	200		
AMA-ERF Campaign	300		
Perinatal Morbidity & Mortality	250		
Emergency Medical Service	150		
Insurance-CSMS Programs	200		
CME Comm. & Accreditation Programs	1,000		
Coop. Comm. Med. Schools of Conn.	200		
Public Relations	400		
Council N.E. State Med. Soc. (Dues)	175		
Comm. Program Scientific Assembly	200		
Judicial Committee	150		
Liaison Comm.-Dept. Income Maint.	150		
Forum for Medical Affairs (Dues)	150		
Professional Liability	1,500		
Statewide Medical Planning	500		
Drug Abuse Educational Program	100		
Maternal Morbidity & Mortality	50		
Allied Medical Services	300		
Medical Aspects of Sports	200		
Auxiliary to CSMS	3,000		
Student Section	3,500		
Resident Section	3,500		
Peer Review	–		
Miscellaneous Committees	100		
	$17,925		
			$230,025

Treasurer's Budget:

Printing & Postage (Coll. of Society Dues)	1,000
Printing & Postage (Coll. of AMA Dues)	800
Certified Accountants (Annual Audit)	1,500
Computer Services (Financial Reports)	700
Commission Expense (Hartford-New Haven)	–
Miscellaneous	100
	$4,100

Executive Office Budget:

Personnel		$269,999
Pension for Mrs. Creighton Barker (6/23/60)		3,000
Office Operation:		41,550
Staff Travel & Misc. Expenses	$11,000	
Office Supplies	1,000	
Maintenance of Office Equipment	1,200	
Printing & Postage	6,500	
Telephone Tolls & Telegrams	1,800	
CSMS Newsletters	10,000	
Sportsmed Publication	4,500	
Subscriptions	300	
News Clipping Service	500	

Addressograph Service	450	
Xerox Rental	–	
Automobile Lease	4,200	
Miscellaneous	100	
	$41,550	
Provision for Social Security Taxes		16,381
Provision for Unemployment Taxes		2,122
		$333,052

Journal Budget:

Personnel			$ 45,128
Manufacturing Cost & Distribution			136,300
Printing		$125,000	
Journal	$116,000		
Roster & Distr.	9,000		
Postage & Handling		10,100	
Reprints		1,200	
		$136,300	
Office Operation:			6,475
Printing & Postage		2,500	
Office Supplies		600	
Telephone Tolls & Telegrams		700	
Sales Tax		150	
Editorial Board Meetings		200	
Editor's Travel (250 mi. radius)		300	
Maintenance of Office Equipment		350	
Subscriptions		300	
Copyrights		250	
Libel/Slander Insurance		500	
Miscellaneous		125	
Advertising Agency		500	
		$ 6,475	
Provision for Social Security Taxes			3,024
Provision for Unemployment Taxes			743
			$191,670

Building Operation:

Municipal Taxes on Building & Equipment	$ 12,225
Comprehensive Insurance	800
Custodial Services	2,900
Building Supplies	800
Electricity, Gas, Water	4,100
Fuel	3,000
Maintenance of Grounds & Snow Removal	1,000
Reserve for Depreciation	2,200
Basic Telephone Service—All Departments	5,000
Repairs & Replacements	1,000
Alarm System	525
	$ 33,550
	$792,397

Anticipated Income over Expense—$21,103

REPORT OF ANNUAL MEETING OF THE AMA HOUSE OF DELEGATES

Chicago, June 19-23, 1983

The AMA House of Delegates met in Chicago, June 19-23. Of the 351 delegates seated, 281 represented state medical associations, 61 represented national medical societies, 9 represented hospital medical staffs, medical students, medical schools, resident physicians, Army, Navy, Air Force, USPHS and the Veterans Administration. The American Hospital Association and American Dental Association sent official observers.

Ronald Reagan, President of the United States, addressing the House of Delegates on Thursday, June 23, said, "the quality of American Medicine is unsurpassed and on that we don't need a second opinion." The President congratulated the AMA on its cost-effectiveness programs and its Health Policy Agenda. He thanked those medical societies that have private sector programs for the needy and unemployed. He supports federal research for medicine and health, hopes that legislation will provide incentives for the private sector to develop drugs to treat rare diseases and favors proposals for a one-year freeze on Medicare physician reimbursement and co-payments for Medicaid.

AMA President, Frank J. Jirka, Jr., M.D., noted in his inaugural address that, "the nation can no longer afford the most expensive (health) care in most expensive settings." He encouraged physicians "to practice medicine in such a manner as to provide appropriate effective care in an appropriate cost-effective setting."

Joseph E. Boyle, M.D., current Chairman of the Board of Trustees, was named President-Elect of the AMA.

An organizational meeting of the HOSPITAL STAFF SECTION was held in conjunction with the AMA House. Over 700 representatives of hospital medical staffs attended. There was great enthusiasm for bringing hospital medical staffs into the AMA policy-making process and giving them an important voice. Thomas C. Peoples, M.D., (Mass) was elected chairman. 7000 hospitals are eligible to send representatives to the Interim Meeting, Los Angeles, December 2-4. The AMA House of Delegates meets December 4-7, 1983.

After in-depth consideration of a Board of Trustees report and extensive debate of 21 resolutions related to the JCAH ACCREDITATION MANUAL for hospitals, the House affirmed a set of principles to be used as the basis of any revisions including the retention of the term "Medical Staff" and the provision for an Executive Staff with a majority comprised of fully licensed physician members appointed from the acting medical staff of the hospital.

A report of the Council on Medical Service, analyzing payment mechanisms, utilized by third party payors for reimbursement for physician services, aroused lengthy discussion. It is the opinion of the Council that a change to an indemnity system of payment would be beneficial to all involved. It was recommended that this subject be considered by constituent societies for possible action at the 1983 Interim Meeting.

The House of Delegates received 74 reports and considered 147 resolutions. Notable actions taken were:

- Added positions for (1) a Resident Physician voting member and (2) a Medical Student non-voting member of the Board of Trustees.
- Filed a report of the Board of Trustees and Council on Medical Service with recommendations regarding future studies of the prospective payment system for hospitals and asked the AMA to promote interest by hospital medical staffs in the DRG process to ensure that quality of care is not compromised and to pursue a program of education and assistance re: DRG to the membership.
- Asked the AMA to conduct a study of the effect of cost-shifting on patients, physicians, third party payors and hospitals.
- Adopted Report F of the Council on Medical Service relative to monitoring the implementation of the Peer Review Program, continuation of support for professionally directed programs of peer review and expansion of activities to provide assistance to state societies when submitting a PRO contract proposal.
- Resolved that the AMA continue to study the care of severely handicapped newborn.
- Requested the AMA to institute an active public information campaign to get accurate information on dioxin before the public and update its 1981 report.
- Called on the AMA to develop advisories for physicians on the AID Syndrome to provide advice to those at risk and encourage research aimed at eliminating the syndrome.
- Commended the Council on Scientific Affairs for its broad review of the use of combined modalities of therapy for cancer.
- Asked the AMA to conduct an investigation of ongoing programs of medical technology evaluation to determine the need for a private/public entity to assess technology, the potential role of the AMA, and seek active participation in the Prospective Payment Assessment Commission established by Social Security Admendments of 1983.

Due to a current favorable financial status, the anticipated dues increase for 1984 was reduced. Regular membership dues are $330.

It is felt that the potential impact on health care which may result from the introduction of the Prospective Payment System for hospitals and implementation of federal government DRG reimbursement programs demands careful monitoring by the profession.

The status of the Connecticut AMA delegation has been strengthened and level of sophistication enhanced by the addition of a Delegate and Alternate Delegate made possible by the increase in the members of the Society.

REPORT FOR CONNECTICUT AMA DELEGATION
Orvan W. Hess, M.D., Chairman
Frank K. Abbot, M.D.
Stewart J. Petrie, M.D.
Guy W. Van Syckle, M.D.
Andrew J. Canzonetti, M.D.
Isadore H. Friedberg, M.D.
Jerome K. Freedman, M.D.
W. Raymond James, M.D.
Daniel W. Doctor, M.D.
William A. Whalen, M.D.

IN MEMORIAM

DWYER, WILLIAM J., Tufts Medical School, 1950. Dr. Dwyer was a general practitioner in the Granby area and was a volunteer with the local police, fire and ambulance services. He was an assistant state medical examiner for many years and participated in the Well Child Clinics of the Granby Visiting Nurse Association. Dr. Dwyer volunteered his services during emergencies in Granby. He was a member of the National Association of Medical Examiners, the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Dwyer died October 28, 1983 at the age of 63.

HERRMANN, ALBERT E., Harvard Medical School, 1923. Dr. Herrmann was surgeon in the Waterbury area since 1929. In 1930, he was appointed to the staff at Waterbury Hospital and became a member of the attending staff in surgery in 1951. Dr. Herrmann was elected president of the medical staff for 1952. From 1955 to 1958, he was Waterbury Hospital's chief of surgery and simultaneously served as its chief of staff in 1958. Dr. Herrmann was transferred to St. Mary's Hospital consulting staff in 1960 and remained in that position until 1978. He retired from private practice in August 1975 and in 1977 was appointed to the honorary staff of surgery at Waterbury Hospital. Dr. Herrmann served with the U.S. Army in Quimper, France, during World War I as a pharmacist and during World War II he served as chief of surgery at Fort Devens with the rank of lieutenant colonel. He was a member of the American College of Surgeons, the New Haven County Medical Society, the Connecticut State Medical Society and the American Medical Association. Dr. Herrmann died December 7, 1983 at the age of 87.

KAPLAN, LEON, Baylor Medical School, 1936. Dr. Kaplan was an opththalmologist in the Bridgeport area since 1940. He was an Army veteran of World War II. Dr. Kaplan was a life member of the Board of Associates at the University of Bridgeport and was past president of Park City Hospital Medical Board. He was past chief of opththalmology at Park City Hospital. Dr. Kaplan was a fellow of the American Academy of Surgeons and the American Academy of Ophthalmology. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Kaplan died November 6, 1983 at the age of 72.

REIDY, JOSEPH C., George Washington University Medical School, 1943. Dr. Reidy was a general practitioner in the Litchfield area from 1947 to 1951 and in 1962 was appointed chief of surgeons at the Litchfield County Hospital, now Winsted Memorial Hospital and served in that capacity for a number of years. He remained a practicing physician until earlier this year. Dr. Reidy entered the Medical Corps during World War II, serving in the Pacific area. He was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Reidy died November 12, 1983 at the age of 65.

RENEHAN, JOHN M., Tufts Medical School, 1928. Dr. Renehan was a general practitioner in the New Haven County area and had been Ansonia city health officer for 35 years. He was a trustee of The Griffin Hospital and surgeon for the Webster Hose Co. Dr. Renehan served on the board of the Hewitt Memorial Convalescent Hospital and had been on the teaching staff of the former Griffin Hospital School of Nursing. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Renehan died November 23, 1983 at the age of 81.

SALVIO, DANIEL G., Padova University, 1957. Dr. Salvio was a general practitioner in the Fairfield area since 1961. He served in the U.S. Army Chemical Warfare service from 1944 to 1947. Dr. Salvio was on the staff of St. Vincent's and Park City Hospitals. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Soceity. Dr. Salvio died July 29, 1983 at the age of 56.

URICCHIO, JOSEPH G., Georgetown, 1931. Dr. Uricchio was a general practitioner in the Hartford area. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Uricchio died November 18, 1983 at the age of 78.

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MANUSCRIPTS should be submitted to the Editor, J. Alfred Fabro, M.D., *Connecticut Medicine*, 160 St. Ronan St., New Haven, CT. 06511. Manuscripts are received with the explicit understanding that they are not simultaneously under consideration by any other publication.

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PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Milford, Connecticut: Free-standing, Walk-In Facility waiting for Board Certified or Prepared Emergency Physician with owner/operator concept. Premises contains 4,000 sq. ft. with x-ray. Located on Long Island Sound with consultants and hospital in Community. Direct inquires to: CARE-INN, 112-120 Broad Street, Milford, CT 06460 (203) 878-5051.

INSTITUTIONAL MEDICINE

PHYSICIANS: Positions available for full-time Directors, and part-time staff in soon-to-be-opened ambulatory care centers in the Hartford, CT area. Applicants must have excellent interpersonal skills with background in Emergency or Family Practice Medicine. Excellent salary and fringe benefits offered. Modern and well-equipped working conditions. Please forward complete C.V. to the following address: 2437 Albany Ave., West Hartford, CT 06117, Attn: Mr. Kevin Young.

INTERNAL MEDICINE

Internist, board certified or board eligible wanted as a full-time staff member of prestigious Hartford HMO with excellent hospital affiliation. Prime opportunity for subspecialists in rheumatology, endocrinology, non-invasive cardiology, gastroenterology with excellent salary and benefits package. Contact Dr. Marci Goldstein (212) 725-1000 collect.

General Internist to associate with established Internist in rural Northeastern Connecticut. Send curriculum vitae to CSMS, IM/SJA.

OBSTETRICS/GYNECOLOGY

B.C. or Eligible OB/GYN wanted to join busy practice in beautiful Northwest Connecticut. Salary guarantee followed by partnership. Respond OB/GYN-RCS.

WANTED: Board eligible or Board Certified Obstetrician/Gynecologist needed to take over 10 year busy practice. Excellent opportunity for female gynecologist. Practice is located in Eastern Connecticut. If interested, contact Ratna R. Srinivas, M.D., 325 Montauk Ave., New London, CT 06320.

PART-TIME

Busy Emergency Department looking for moonlighter or part time physician. Previous E.R. experience required. Please contact George J. Terranova, M.D., Chairman, Emergency Department, Danbury Hospital, Locust Avenue, Danbury, CT 06810. Phone (203) 797-7405.

MEDICAL DIRECTOR. A newly developed non-profit alcoholism treatment center in Central Connecticut offering comprehensive and innovative inpatient, outpatient and partial hospitalization services invites candidates to apply for the part-time position of Medical Director, available December 1, 1983. Candidate of interest will be an M.D. with specialized expertise in treatment of medical complications of alcoholism. Board eligibility or certification in Internal Medicine, clinical administration experience and teaching ability preferred. Salary commensurate with experience and qualifications. Send resumes in confidence to CSMS, PT/RD.

PART-TIME—Continued

CONTRACT PHYSICIAN—part time—to work on-site at the main Post Office, Hartford, CT. For further information, contact: Area Medical Officer, 141 Weston Street, Hartford, CT 06101. Tel. 203-524-6046

SURGERY

GENERAL SURGEON. Board Certified or Board Eligible individual for community based practice in a delightful growing area, Northwest Connecticut, with a progressive small hospital and a young well trained staff. Reply with CV to: Mrs. Barbara Blank, Medical Staff Secretary, New Milford Hospital, 21 Elm St., New Milford, CT 06776.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

EMERGENCY ROOM

Immediately available. Age 42. Licensed in Connecticut. MD, Kurnool Medical College, Vkjayawada, A.P., India; Int., Government General Hospital, Kurnool; Res., St. James University Hospital, Keighley, U.K. Has had training in the United Kingdom in Orthopedics and Anesthesiology. Prefers group or institutional type practice. Write, K.B. Santhappa, M.D., 5715 Eunice Court, Richmond, VA 23228.

Nov. '83. Age 45. Nat'l bds. MD, University of Innsbruck, Austria; Int., Unity Hospital, NYC; Res., St. Francis Medical Center, Trenton, NJ. Prefers associate or institutional type practice in a medium-sized community. Write, Imran A. Shilleh, M.D., 6 Pinnacle Rock Rd., Stamford, CT 06903.

FAMILY PRACTICE

July '84. Age 28. Nat'l bds. AB elig. MD, University of Connecticut, Storrs; Int. and Res., Somerset Medical Center, Somerville, NJ. Practice to include pediatrics adult medicine, and office gynecology but no obstetrics. Prefers group or associate type practice in a small to medium-sized community. Write, Peter L. Anderson, M.D., 1122B Easton Ave., Somerset, NJ 08873.

Nov. '83. Age 34. Licensed in Connecticut. Presently in practice. Nat'l bds (FLEX). AB elig. MD, Faculty of Medicine, University of Seville, Spain; Int., University Hospital, Seville; Res., St. Mary's Hospital, Hoboken, NJ. Prefers solo, group, associate or institutional type practice. Would consider solo practice if a community is in need of a physician and is willing to provide financial aid for start up practice. Write, Jaime F. Lara, M.D., 6045 Palisade Ave., West New York, NJ 07093.

INTERNAL MEDICINE

July '84. Age 33. Licensed in Connecticut. AB elig. MD, Dow Medical College; Int. and Res., New Britain General Hospital. Prefers solo, group and established practice to buy. Write, CSMS, SH/IM.

ENDOCRINOLOGY. July '84. Age 30. Nat'l bds. AB cert. MD, SUNY Upstate, Syracuse, NY; Int., Res. and Fellowship, University of Maryland, Baltimore, MD. Desires group or associate type practice in a medium to larged-sized community. Write, Elliott Friedman, M.D., 25 Penny Lane Baltimore, MD. 21209.

INTERNAL MEDICINE—Continued

July '84. Age 28. Nat'l bds. AB elig. MD, University of Virginia; Int. and Res., University of Massachusetts Medical Center. Prefers group, associate or solo type practice in medium-sized community. Write, Bruce A. Kahan, M.D., 180 Worcester St., Bldg III-6, West Boylston, MA 01583.

July '84. Age 26. Nat'l bds. AB elig. MD, Boston University School of Medicine; Int. and Res., Boston University Hospital; Fellowship, Mount Sinai Hospital, NYC. Prefers group or associate type practice in a small to medium-sized community. Write, David L. Oshin, M.D., 30 W. 61st St., Apt. 6D, New York, NY 10023.

CARDIOLOGY. Sept. '83. Age 42. Presently in practice. Nat'l bds. AB cert. MD, SUNY; Int. Beth Israel Hospital, NYC; Res., Beth Israel Hospital and University of Michigan Medical Center, Ann Arbor; Fellowship, Montefiore Hospital and Medical Center, NYC. Prefers group, associate or institutional type practice in a small to medium-sized community. Although fully catheter trained, prefers to practice non-invasive clinical cardiology. Write, Gary P. Schwartz, M.D., 8 Lodge Dr., Rockville, MD 20850.

GASTROENTEROLOGY. July '84. Age 32. Nat'l bds. AB cert. MD, New York University; Int. and Res., Lenox Hill Hospital, NY; Fellowship, NY Medical College. Skilled in all diagnostic and therapeutic procedures. Prefers group or associate type practice. Write, CSMS, SW/IM.

GASTROENTEROLOGY. Jan. '84. Age 32. AB elig. MD, Universidad Autonoma de Guadalajara, Guadalajara, Mexico; Int. and Res., City Hospital Center at Elmhurst, Elmhurst, NY. Fellowship, Hershey Medical Center, Hershey, PA. Prefers solo or associate type practice in a small community. Write, Gerald S. Weinstein, M.D., 1123 Summerwood Drive, Harrisburg, PA 17111.

MEDICAL ONCOLOGY. July '84 or '85. Age 32. AB elig. MD, Akademia Medyczna w Poznaniu; Int., University Hospital, Lubumbashi; Res.; Ottawa Civic Hospital, Ottawa, Canada; Fellowship, Princess Margaret Hospital, Toronto. Prefers solo, group or associate type practice in a large-sized community. Write, Rafal Wierzbicki, M.D., 41 Spruce St., #7, Toronto, Ontario, Canada, M5A2H8.

OBSTETRICS/GYNECOLOGY

Oct. '84. Age 29. Nat'l bds. AB elig. MD, St. Louis University Medical School; Int. and Res., St. Louis University Hospitals. Prefers group or associate type practice. Write, Thomas J. Helm, M.D., 4429 A. Rosa Ave., St. Louis, MO 63116.

Oct. '84. Age 29. Nat'l bds. AB elig. MD, St. Louis University Medical School; Int. and Res., St. Louis University Hospitals. Prefers group or associate type practice. Write, Charles Helm, M.D., 4429 A. Rosa Ave., St. Louis, MO. 63116

Sept. '83. Age 58. Nat'l bds. AB cert. MD, Medical College of Wisconsin; Int., Kings County Hospital, NY; Res., State University of NY, Downstate; Fellowship, Long Island University, NY. Prefers institutional or industrial type practice in a medium to large-sized community. Interested in Public Health Administration. Write, Thomas F. Sullivan, M.D., M.P.A., 5 Briarwood Lane, Suffern, NY 10901.

Nov. '83. Age 31. Nat'l bds. AB elig. MD, Harvard; Int. and Res., George Washington University Medical Center, Washington, DC. Prefers group or associate type practice in a medium-sized community. Looking for a situation in southwestern Connecticut. Would like a University affiliated hospital. Write, Corinne E. de Cholnoky, M.D., 224 West Lyon Farm, Greenwich, CT 06830.

OPHTHALMOLOGY

July '84. Age 29. Nat'l bds. AB cert. (Pediatrics). AB elig. (Ophthal). MD, Chicago Medical School; Int., North Shore University Hospital (Pediatrics); Res., North Shore University Hospital (Pediatrics) and State University of NY, Downstate Medical Center (Ophthal). Prefers group or associate type practice. Although trained in all aspects of ophthalmology would like to practice general ophthalmology with an emphasis on pediatric eye diseases. Write, Andrew E. Gewirtz, M.D., 519 Beach 133 St., Belle Harbor, NY 11694.

ORTHOPEDIC SURGERY

Spring 1984. Age 36. Presently in Practice. Nat'l bds. AB elig. MD, SUNY at Buffalo; Int., Upstate Medical Center; Res., Bronson-Borgess, Kalmazoo, MI. Prefers solo, group, associate, institutional, or industrial type practice in a medium to large-sized college town. Write, Gerald Coniglio, M.D., 238 Bewley Building, Lockport, NY 14094.

July '84. Age 30. Nat'l bds. AB elig. MD, Downstate Medical Center-SUNY; Int. and Res., Maimonides Medical Center, NY. Prefers group, associate or hospital practice in a large-sized community. Write, Richard Lebovicz, M.D., 415 Grand St., New York, NY 10002.

PATHOLOGY

July '84. Age 30. Nat'l bds. AB elig. MD, NY University; Int. and Res., Medical College of Virginia. Prefers group, associate or institutional type practice. Write, Mark A. Grathwohl, M.D., 2510 West Tremont Court, Richmond, VA 23225.

PEDIATRICS

Jan. '84. Age 50. Presently in practice. MD, National University of Corboba, Argentina; Int. and Res., Children's Hospital of Cordoba. Prefers group practice in medium-sized community. Write, Aida M.E. Puszkin, M.D., c/o Max Staubli, 11 Tanglewood Dr., Avon, CT 06001.

Oct. '83. Age 29. Licensed in Connecticut. FLEX. AB elig. M.B.B.S., Osmania University; Int., Rutgers Medical School; Res., UCONN and Waterbury Hospital. No preference to size and type of practice. Write, Rukmini S. Kenia, M.D., 295 High Path Rd., Windsor, CT 06095.

Immediately available. Age 31. Presently in practice. Nat'l bds. AB cert. MD, University of Pittsburgh; Int. and Res., Geisinger Medical Center; Fellowship, Medical College of Georgia (Pediatric Neurology). Desires group or associate type practice in a small to medium-sized community. Write, Roderic J. Hartman, M.D., 2104 Berskhire Drive, Monroeville, PA 15146.

July '84. Age 27. Licensed in Connecticut. FLEX. AB elig. MD, Downstate Medical School (SUNY); Int., University of Vermont, Burlington, VT; Res., University of Vermont and University of Connecticut, Farmington. Prefers group type practice. Write, Rita Iovino, M.D., 36 Lilley Rd., West Hartford, CT 06119.

SURGERY

June '84. Age 35. Nat'l bds. AB elig. MD, University of Illinois; Int. and Res., St. Josephs Hospital, Denver, CO. Prefers group or associate type practice in a medium-sized community. Write, Alfred G. Garcia, M.D., 307 So. 2nd St., Wilmington, NC 28401.

July '84. Age 31. Nat'l bds. AB elig. MD, NY Medical College, Valhalla, NY; Res., Wayne State University, Detroit, MI. Prefers group practice in a medium to large-sized community. Write, Robert S. Bloch, M.D., 27300 Franklin Rd., #214, Southfield, MI 48034.

July '84. Age 31. Nat'l bds. AB elig. MD, Rutgers Medical School; Int., and Res., Georgetown University Hospital. Prefers associate, group, solo or institutional type practice in that order. Also, prefers small to medium-sized community to practice. Write, Richard S. Murray, M.D., 1920 N. Calvert St., #303, Arlington, VA 22201.

UROLOGY

July '84. Age 36. Nat'l bds. AB elig. MD, State University of NY at Buffalo; Res., Buffalo General Hospital and SUNY at Buffalo (General Surgery) and Buffalo General Hospital and SUNY at Buffalo General Hospital (Urology). Prefers solo, group or associate type practice in a medium to large-sized community in a University town. Write, CSMS, BSL/UR.

Oct. '84. Age 34. AB elig. MD, Universidad Automoma de Guadalajara, Guadalajara, Mexico; Int., C.M.D.N.M., Rutgers Division (Surgery); Res., Hahnemann Medical College & Hospital and West Virginia University Hospital (Urology). Prefers group or associate type practice in a medium-sized community. Write, CSMS, UR/JGC.

The Clinical Use of Specific Monoclonal Antibodies to Human IgE in Allergy Diagnosis

ROBERT S. GILLCASH, M.D. AND HEZEKIAH KAMUZORA, PH.D.

ABSTRACT—The in vitro diagnostic tests for total and specific IgE for IgE-mediated allergies are becoming useful clinical tools. This paper discusses a new in vitro assay (IgE FAST™ Test) that utilizes a monoclonal anti-IgE antibody. To test the clinical usefulness of this assay, we initiated a study in which 1,069 patients participated. Eight cases are presented in this paper. All patients had positive skin tests for various inhalent antigens. Skin and monoclonal antibody testing correlated well ($r = 0.89$) in patients who had not been on immunotherapy. A significant reduction in IgE levels was observed in patients who had been on prolonged immunotherapy and who had clinical improvement. This test opens an important avenue of allergy diagnosis for the clinician.

In the past several years, enormous strides have been made in the diagnosis and treatment of allergy. With the discovery of Immunoglobulin E by Ishizaka and Johansson, a new insight into the mechanism of the human allergic response has emerged.[1,2] The identification of IgE antibody against specific allergens is becoming increasingly important, and in vitro tests that measure IgE titers are becoming more useful and accurate.

Skin testing has historically played a key role in the diagnosis of allergy; however, there has always been a need for a clinically specific, reproducible, and standardized in vitro test procedure.[3] To this end, a number of methods have been developed to measure circulating IgE antibody levels. The first generation of these tests which employed a radioimmunoassay (RIA), such as the RAST, were generally regarded as having greater specificity, but less sensitivity than skin testing.[4,5] Polyclonal antibodies are used in these radioimmunoassays; consequently, the likelihood of cross reactivity with nonspecific allergens is always present. Radioimmunoassays have proved to be time-consuming, and as they must be conducted in an NRC licensed facility, are not always practical for in-office use. Thus, we sought a less cumbersome, more sensitive method of allergy diagnosis for our laboratory. We selected a new enzyme-linked fluorometric sandwich-type immunoassay which utilizes a monoclonal anti-IgE antibody (IgE FAST™ Test, i.e., a fluorescence allergo sorbent test).

We initiated a study to determine whether the IgE FAST Test assay provided specific, sensitive, and reproducible results, and whether test results were closely correlated with the patient's clinical history and symptoms. In this paper, we present eight cases among the 1,069 patients who participated in this study. Data indicate a strong correlation between test values and symptoms. They also suggest that this test provides a reliable means of determining whether the positive skin test is IgE-mediated.

Methods

All patients participating in this study were selected from a large ENT practice. All presented with symptoms typical of inhalent allergy, and all were tested by the serial end point titration method.[6] RAST assays were either run simultaneously or subsequently. After the recent introduction of the IgE FAST Test, the sera of all 1,069 patients were tested by this assay. The IgE FAST Test was conducted according to a protocol set forth by the manufacturer.* In it, the allergen of interest

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Reprints requests to: 36 Watson Street, Willimantic, CT 06226 (Dr. Gillcash).

*Allergenetics, Mountain View, California is attached to a microtiter plate well. The allergen-specific IgE in an added patient serum sample binds to the attached allergen. Nonspecific IgE is washed away after the appropriate incubation. Enzyme-labeled monoclonal anti-IgE is added and binds to the IgE remaining in the well. Excess anti-IgE is washed away and a fluorogenic substrate is added. After a fixed time interval, the degree of fluorescence emitted by the substrate is measured by a microtiter fluorometer. The greater the fluorescence emitted from each well, the higher the amount of specific IgE contained within. To qualify test results, the fluorescence measured from each well is compared directly with the fluorescence of reference sera run in parallel. Data are presented in International Units of IgE; these units, as seen in Table 1, relate to standard class scoring systems.[5]

Table 1

Class Score	*Specific IgE Conc. (u/ml)*	*CLINICAL EVALUATION*
O	<0.02	Very low or below detection
I	0.02 - 0.1	Equivocal
II	0.1 - 0.5	Increasing Levels
III	0.5 - 2.5	of
IV	2.5 - 12.5	Antigen Specific
V	12.5 - 62.5	IgE Antibodies
VI	>62.5	

Case Reports

Case 1: This 37-year-old female had a long history of nasal congestion, eustachian tube malfunction, and a diminished sense of smell and taste. She also had vasomotor problems. The patient reported an allergy to cats, and she had not responded to antihistamines. Her total IgE was 20 IU/ml (Figure 1).

Case 2: The patient is a 13-year-old girl with a three-year history of otitis media, nasal stuffiness, and conjunctivitis. She reported a progressive worsening of her symptoms which prompted her to seek medical care. She had not been started on immunotherapy at the time she was tested. She had a total IgE of 210 IU/ml (Figure 1).

Case 3: The patient is a 23-year-old woman who presented with a history of repeated sore throats and stuffy, itchy nose. Her total IgE was 195 IU/ml (Figure 1). At the time of the test, she had not started immunotherapy.

Case 4: This 45-year-old female had postnasal drip, headache, conjunctivitis, and nasal stuffiness. She was found to have infectious sinusitis which required surgery. After surgery, her allergic symptoms remained. She has not responded well to immunotherapy. Her total IgE when first tested was 47 IU/ml (Figure 2).

Case 5: The patient is a 12-year-old boy with nasal congestion and a strong ENT allergic history. In 1979, his total IgE was 480 IU/ml. Sinus x-rays were clear. The parents thought the boy was sensitive to cats. He has had four years of relief with immunotherapy; his total IgE is now 76 IU/ml (Figure 3).

Case 6: This 31-year-old man had a seven-year history of nasal congestion, postnasal drip, and conjunctivitis. When first seen in 1976, his total IgE was 215 IU/ml. The patient has responded favorably to immunotherapy and his total IgE is now 90 IU/ml (Figure 3).

Case 7: This 33-year-old woman had a questionable allergy to penicillin, postnasal drip, and headache over a 10-year period. Her condition worsened three months prior to being seen in our clinic. When initially tested, her total IgE was 14 IU/ml. RAST scores for inhalent antigens were negative. Skin testing indicated she was sensitive to inhalent antigens. Immunotherapy was begun on the basis of skin testing despite low RAST scores. Her symptoms have improved greatly. (Figure 3).

Case 8: This patient is a 54-year-old woman with long history of headaches. In 1981, sinus x-rays were clear. Her initial IgE was 13 IU/ml. She had a positive skin test, and responded well to immunotherapy. (Figure 3).

Results

The correlation between IgE FAST Test scores and skin testing in cases 1-3 is shown in Figure 1. These patients were part of a group of 47 patients who had not started immunotherapy at the time they were seen. In these 47 patients, we observed a strong correlation (r = 0.89) between FAST scores and skin testing.[7]

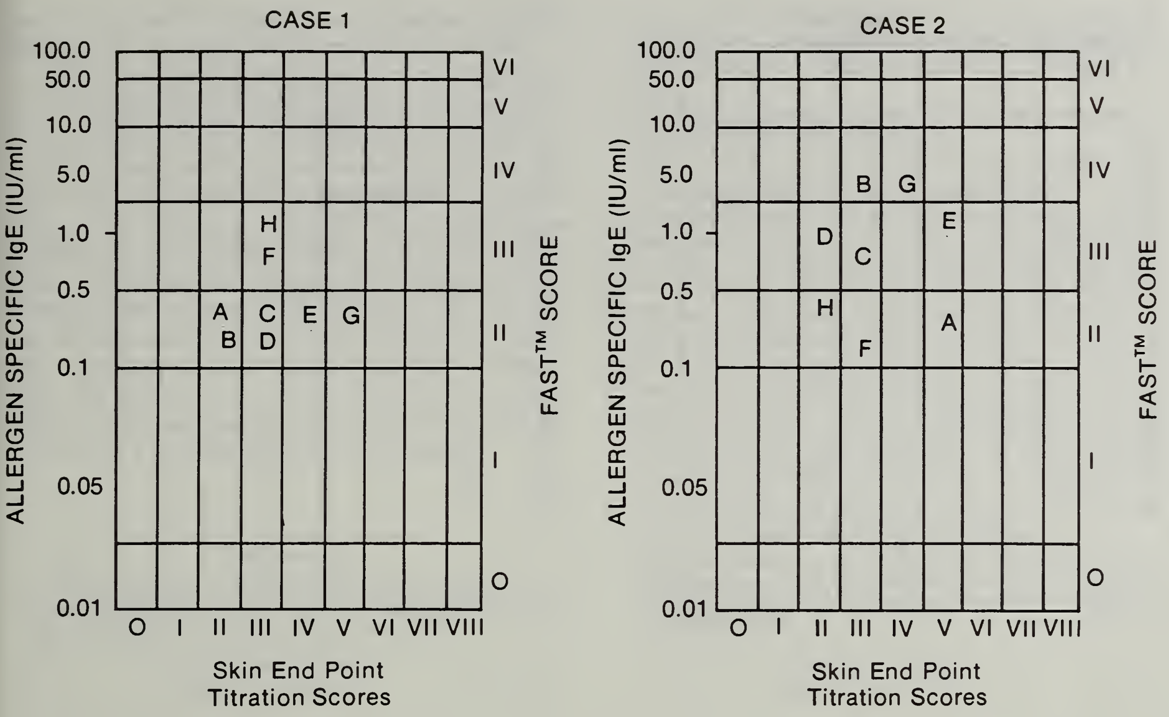
Case 4 (Figure 2) is an example of a patient with a low total IgE value who did not respond to immunotherapy. The skin test, which was performed at the time of the initial evaluation, was positive. Current IgE values are consistent with the clinical picture. Patient #4 was one of a group of 11 nonresponders. No attempt was made to correlate the original skin test data and current FAST data

Cases 5-8 were part of a group of 1,011 patients, all of whom had symptoms and original skin test results that supported the diagnosis of allergy. Patients presented in this group improved with immunotherapy. As in case 4, we made no attempt to correlate original skin test and current IgE FAST Test results. However, in these patients, FAST test data confirm the reduction in specific and total IgE values that was consistent with the patient's improved health.

Discussion

In recent years, great strides have been made in the in vitro diagnosis of allergic diseases. However, the value of these tests remains controversial. Our data demonstrate that the IgE FAST Test offers physicians an opportunity to provide quality medical services which previously have not been available. Certainly in the workup of some patients, being able to rule out allergy is very significant. We have shown that we can confidently rule out allergy on the basis of the in vitro IgE FAST Test. Furthermore, our data indicate that this test provides an objective means of monitoring immunotherapy.

In vitro allergy diagnosis offers several advantages over skin testing. Convenience and economy are important factors. A diagnosis of multiple allergies can be made from a single blood sample. Patients, therefore, are spared the necessity of multiple office visits and numerous skin tests. There is no physical discomfort to patients, and there are no false positive reactions secondary to nonspecific irritants. In addition, in vitro testing is the procedure of choice in infants and small children who are unwilling or unable to cooperate with standard skin testing methods. Elderly patients with poor skin tone, patients on medications such as antihistamines or steroids, asthmatics in whom skin testing might be dangerous, and those patients with skin disorders whose skin is difficult to read all make suitable subjects for this



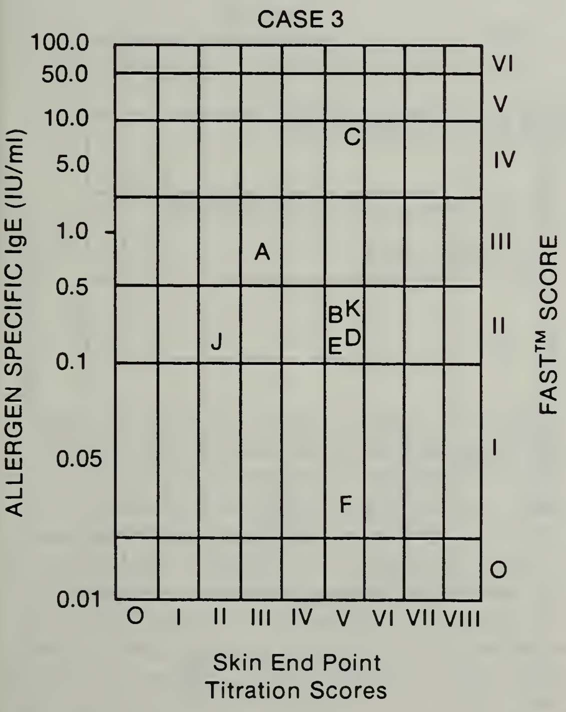


Figure 1
Case 1,2, and 3
In vitro IgE FAST Test scores and skin endpoint titration scores in allergic patients prior to immunotherapy.

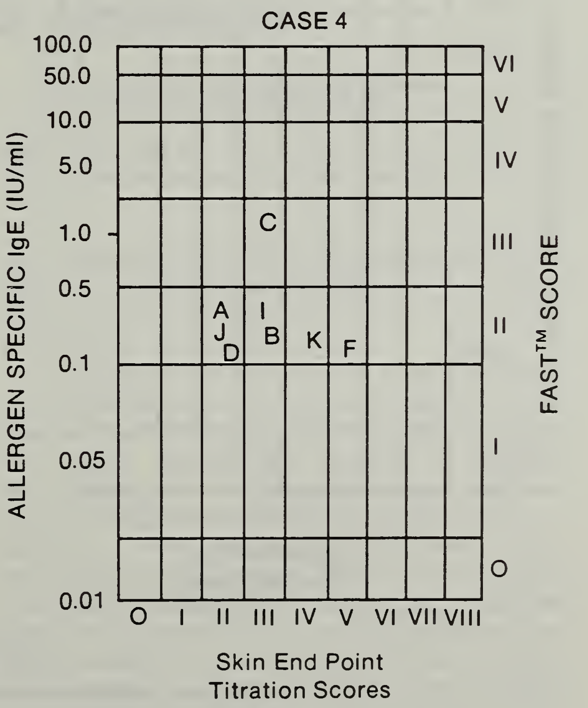


Figure 2
Case 4
Example of patient with low IgE that has not responded to immunotherapy. Skin test data was obtained at time patient started immunotherapy. IgE FAST Test is current data.

FIGURE LEGEND FOR GRAPHS

A—Alternaria
B—Maple
C—Short Ragweed
D—June Grass
E—Dust Mite
F—English Plantain
G—Cat
H—Dog
I—Birch
J—Aspergillus
K—House Dust

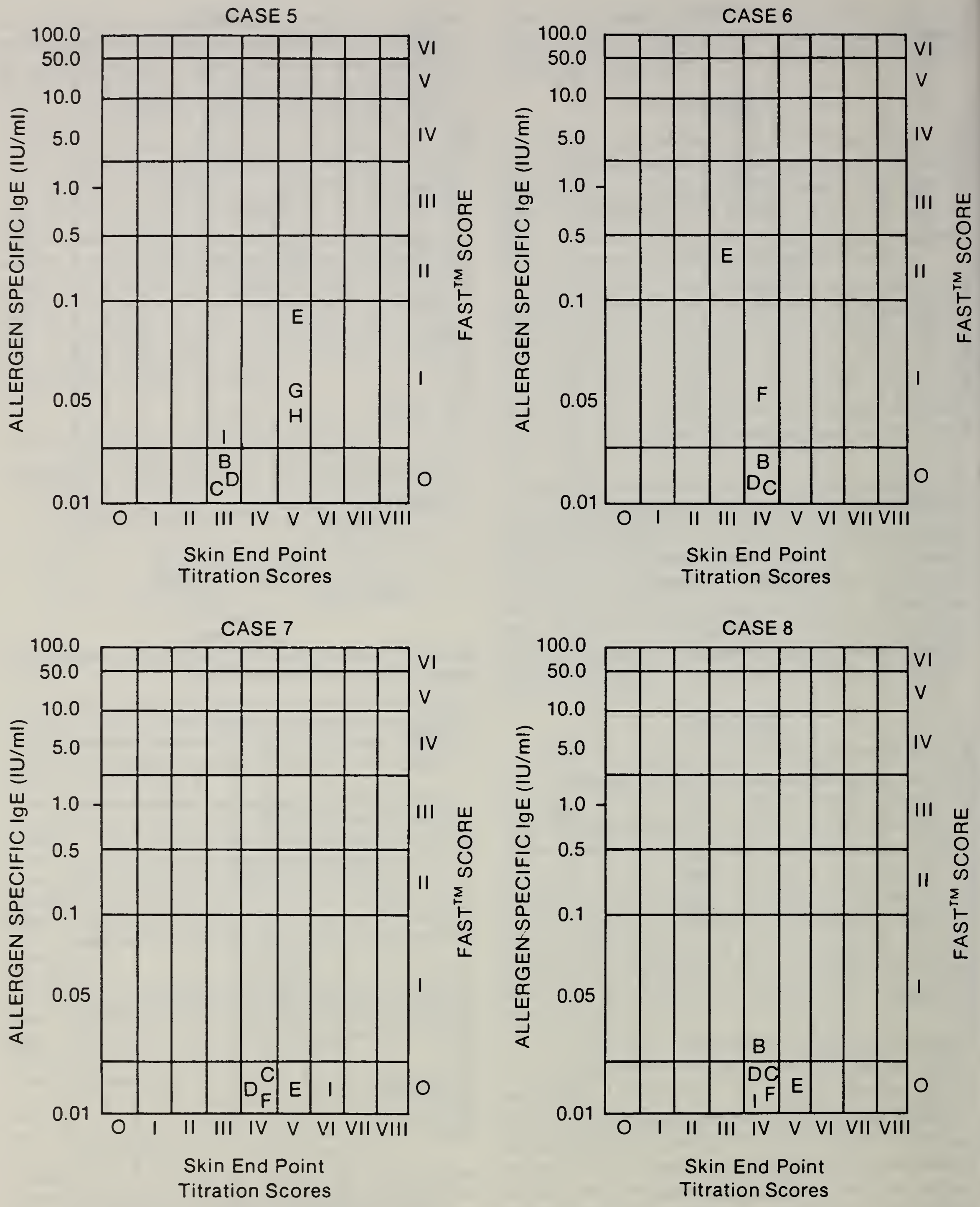


Figure 3
Case 5, 6, 7, and 8
Examples of patients with symptoms and skin test results consistent with allergy. All patients are on immunotherapy and have responded. Current IgE FAST Test data is supported by lowered IgE and improved symptom ontology.

procedure as well. The results can be used as a reliable indicator for selecting therapy modes.

The data in our study support previously published data that allergy can be diagnosed by in vitro testing in 80% of patients.[8] There are conditions other than IgE-mediated allergy which elevate the total IgE score, and which must be considered in the diagnosis. These include chronic urticaria, parasitic infections such as ascariasis, and Hodgkin's disease.[9] In the face of a strong clinical history of allergy which is associated with elevated levels of total IgE, specific IgE in vitro tests such as the monoclonal IgE FAST Test may be reliably used for diagnosis. If the total IgE is in the low normal range and the patient has a strong history of clinical allergy, individual specific IgE in vitro tests that are positive are a valuable adjunct to skin testing.

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Outpatient Digital Angiography

GERALD S. FREEDMAN, M.D., WILLIAM E. ALLEN, M.D.

AND BRUCE D. SIMONDS, M.D.

Digital Angiography applies the power of computers to the study of blood vessels with the same dramatic results that occurred when Computerized Tomography was applied to the study of the head.[1-4] Improvements in image enhancement by computers make possible the visualization of the arterial system from intravenous injection of contrast media. Arteries may now be studied with significantly reduced risk, discomfort and expense. The concept of image subtraction is not new. Early studies required large volumes of contrast media, large needles, and photographic subtraction of unprocessed information.[5-7] In 1977, digital video image processors were introduced. Digital Subtraction Angiography (DSA) was the most useful clinical technique to evolve from this technology and was commercially introduced as a prototype version in November of 1980.

In the spring of 1981, our office was selected to evaluate the feasibility of outpatient digital angiography in a private practice. Our facility was chosen due to our comprehensive imaging capability and experience in outpatient special procedures. After several months, the results were so encouraging that the prototype was replaced by a production unit. The digital image processor was added to an existing late model 3-phase fluoroscopic room which was modified by adding a new imaging chain (high heat x-ray tube, improved image intensifier and state-of-the-art TV camera). Our experience over the past two years has established the safety and efficacy of this procedure on an outpatient basis. Over 1,900 patients have been studied by this technique; their clinical profile is shown in Table 1, demonstrating the emphasis on cervicocerebrovascular disease.

GERALD S. FREEDMAN, M.D., Director, Temple Radiology Group; Associate Clinical Professor of Diagnostic Radiology, Yale University School of Medicine; Adjunct Professor of Radiology, Vanderbilt University. WILLIAM E. ALLEN, M.D., Associate Clinical Professor of Diagnostic Radiology, Yale University School of Medicine. BRUCE D. SIMONDS, M.D., Assistant Clinical Professor of Diagnostic Radiology, Yale University School of Medicine.

Table 1
18 MONTH EXPERIENCE–MAY '81-NOV '82

Patients	1005
Examinations	1030
Carotids	890
Renal	50
Abd. Aorta	32
Subclavian	36
Femoral	16
Aortic Arch	12
Iliac	8
Cardiac	7
Pulmonary	3
Hip Arthrogram	3

Technique

All patients have been studied by a central venous injection. In 97% of the cases, an antecubital vein is catheterized by a percutaneous Seldinger technique. A 5.3 French (or smaller) six-side hole pigtail catheter is advanced to the junction of the right atrium. A femoral approach has been needed in less than 3% of our patients. A 20-30cc bolus of contrast media is power-injected at a rate of 20-25 cc's per second. Three to five injections are usually required for each study. Our clinical experience is summarized in Table 2. No serious complications have been encountered in the first 1600 patients. There have been no extravasations. In two instances, proper placement of the catheter could not be accomplished. During our initial experience, three cases of superficial phlebitis were encountered; improved technique with smaller catheters and reduced time appears to have eliminated this problem. Patients with impaired cardiac or renal function must be carefully monitored to avoid congestive heart failure or acute tubular necrosis from the contrast load. Fortunately, no serious allergic reactions were encountered, although this remains the solitary significant potential hazard.

Table 2
CLINICAL EXPERIENCE

Patients	1000
Femoral Cath.	30
Failures	2
Complications	
Angina	6
Pulmonary Edema	3
A.T.N.	1
Phlebitis Arm	3
Allergic	none serious

Cervicocerebrovascular Disease

Approximately 85% of our patients are referred with this diagnosis. Earlier noninvasive screening studies (nuclear flow medicine, doppler, and washout studies) have all been unreliable in certain circumstances. Significant stenosis and plaques may be missed and assessment of the vertebrals can be difficult. However, the risk of arterio-catheterization in association with high hospitalization costs and poor patient acceptance makes carotid arteriography unacceptable as a diagnostic screening tool.

Presently, our standard DSA study for cervicocerebrovascular disease uses four separate views. A right posterior oblique for the aortic arch and origin of the great vessels, a right and left posterior oblique for the carotid bifurcation (Figure 1), and an anteroposterior Towne or Caldwell view for intracranial circulation (Figure 2). The quality of the resulting images is dependent upon patient cooperation and cardiac output. Motion during the computer recording of the data will result in image degradation; involuntary swallowing alone may cause serious registration defects. A recent computer improvement (array processing) permits image reregistration of the data to overcome certain motion artifacts. Reduced cardiac output can only be partially overcome by larger amounts of contrast media, which is undesirable in patients with congestive heart failure. Unfortunately, a significant number of patients undergoing DSA studies are in an age group where carotid and cardiac disease often coexist. Each study is individually tailored to evaluate the clinical presentation. Typical symptoms include bruit, transient ischemic attack, amaurosis fugax, or stroke. The image quality of our studies has been steadily improving (Figure 3). In approximately 90% of our patients, adequate visualization of the vessels is accomplished. Our experience parallels the reports of other investigators.[8,9] The follow-up analysis of 690 patients is shown in Table 3. Physician and patient acceptance of the procedure was excellent. Many patients went on to definitive procedures without the need for arteriography. Several have been restudied postoperatively to evaluate the status of endarterectomies or bypass graft.

The problem of superimposition of vessels caused by the simultaneous opacification of all vessels in the area has been substantially reduced by the recent installation of a C-arm x-ray tube and 12-inch image intensifier (Figure 4). This apparatus allows 360 degree rotation about the patient axis as well as caphalad-caudad angulation. The larger image intensifier tube is suitable for evaluation of the abdomen and chest.

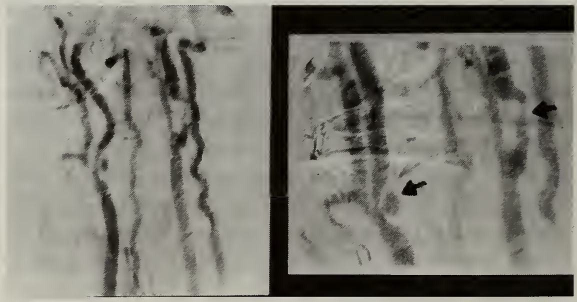

Figure 1
On the left is a 9-inch view in the right posterior oblique projection, demonstrating the carotids and vertebral vessels. Abnormalities of both internal carotid origins are better seen on a repeat injection using a 6-inch magnification and a slight change in obliquity to eliminate superimposition of the left vertebral. The magnification image clearly shows an ulcerative plaque at the origin of the right internal carotid with a 90% stenosis and an irregular plaque at the origin of the left internal carotid with perhaps a 70% stenosis.

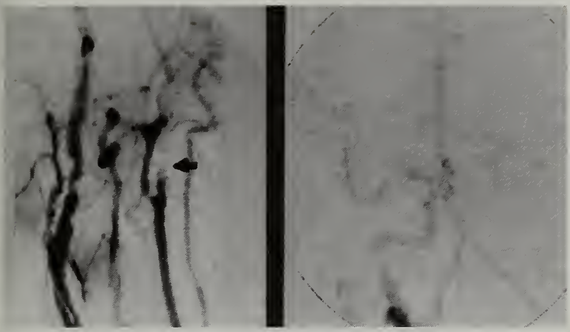

Figure 2
This is a 9-inch left posterior oblique view of the neck showing a completely occluded left internal carotid and irregular atheromatous disease along the right internal carotid. An anteroposterior Towne view shows no flow in the left internal carotid and reduced flow in the left middle cerebral, consistent with the occlusions seen in the neck.

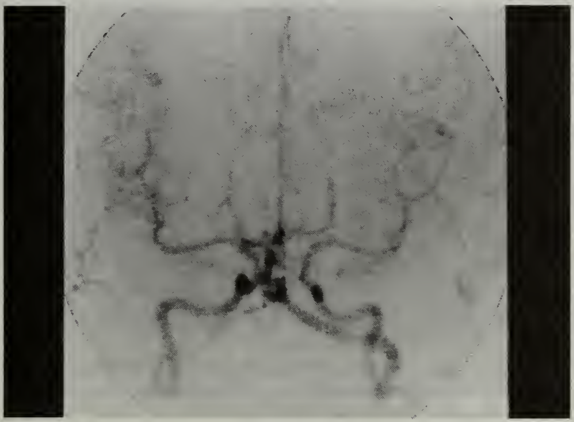

Figure 3
This normal AP Towne view shows a dominant left vertebral artery. Note the excellent resolution of the intracranial vessels in a patient with good cardiac output and no disease.

Table 3
FOLLOW UP

Exams	690
Patients	651
Male/Female	50/50
Pos/Neg	55/45
Responses	373
Surgery	89
No Other Exam	59
Additional Exams	94
Angiogram	37
Ultrasound	24
CT	19
Misc.	14

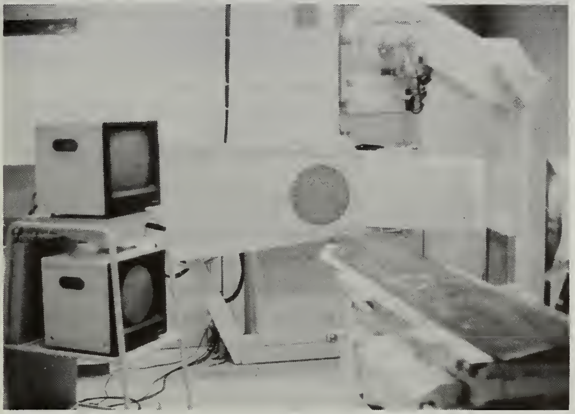

Figure 4
Our new digital angiographic suite features a C-arm configuration for the X-ray tube, allowing a 360-degree rotation and cephalocaudad angulation. The image intensifier (under the pedestal table in this view) has a 6, 9, or 12-inch capability.

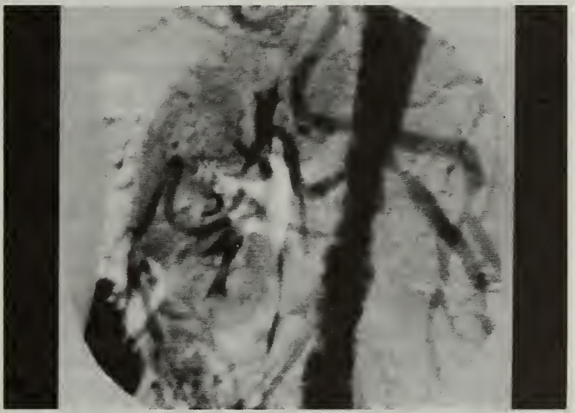

Figure 5
This prone image shows atheromatous disease of the abdominal aorta with a stenosis at the origin of the right renal artery.

Major Vessel Disease

DSA is particularly useful in demonstrating the major vessels.[10] Our clinical experience includes the following: thoracic outlet syndrome, coarcation of the aorta, aneurysms of the aortic arch and thoracic and abdominal, aorta pulmonary embolism, renal artery stenosis, false aneurysms, AV malformation, arteriosclerotic and occlusive disease of the lower abdominal aorta and iliac vessels (Figure 5). Often, DSA can demonstrate the reconstitution of vessels following an occlusion due to the system's extreme sensitivity to the detection of dilute contrast media.

The importance and efficacy of DSA in the evaluation of renal artery hypertension have been well documented.[11] The images successfully demonstrate major stenosis, as well as fibromuscular renal artery disease. In comparison with conventional arteriography, the sensitivity and specificity for renal artery stenosis was 93% and 91.5% respectively.[12] The cost effectiveness and role of DSA in hypertension and its ultimate management by percutaneous transluminal angioplasty have been shown. Although we have not had experience with renal transplants, its use has been advocated by others[13] for the evaluation of the renal donor and graft recipient preoperatively and post-operatively to monitor for renal artery stenosis and immunologic rejection.

Large renal masses or retroperitoneal masses are within the capabilities of the system. The finer tumor vascularity demonstrated by selective magnification angiography cannot be accomplished due to the resolution limits of the system (Figure 6).

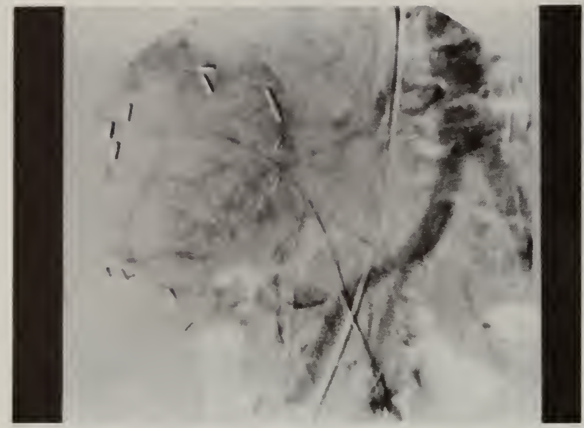

Figure 6
This shows a recurrence of a retroperitoneal tumor supplied directly by branches arising from the abdominal aorta just above the bifurcation. Note: This patient was catheterized from a femoral approach.

A limitation of the system in the abdomen results from abdominal gas movement due to peristalsis during the time of the data collection. This results in a complex reregistration artifact, which is difficult to eliminate. Some success has been achieved by studying these patients in the prone position, thereby displacing the gas from the central field. Earlier limitations of field size, with the 9-inch image intensifier, have been overcome by the recent installation of our 12-inch image intensifier. Our initial digital angiographic room has been particularly useful for the evaluation of patients with thoracic outlet syndrome. Since the table is a modified 90-degree fluoroscopic unit, patients can be studied in an upright or semi-erect position, thereby duplicating the anatomical position which produces the most symptoms. Dramatic temporary occlusions have been produced in the upright position with the arm elevated, which completely disappear with the arm in neutral position or the patient recumbent.

Evaluation of the most distal vessels can be adequately demonstrated by intravenous DSA in normal patients to below the elbow or knees. However, patients with significant arteriosclerotic and peripheral vascular disease cannot be adequately studied due to the small fraction of the cardiac output delivered to these limbs. While intravenous DSA is usually sufficient to demonstrate the major occlusion and is sometimes helpful in demonstrating collaterals due to the high contrast sensitivity, the distal vessels are sometimes not adequately visualized. Recently, we have used small amount of contrast media introduced directly into a distal artery to better evaluate these smaller vessels. Excellent visualization can be accomplished by this technique which uses small amounts (2-5cc's) of dilute contrast media directly introduced into the artery by a percutaneous needle stick. The low contrast concentration is well tolerated by the patient and produces good resolution images of the distal vessels. An example of the interosseous vessels of the hand and branches of the distal radius and ulnar are shown in Figure 7.

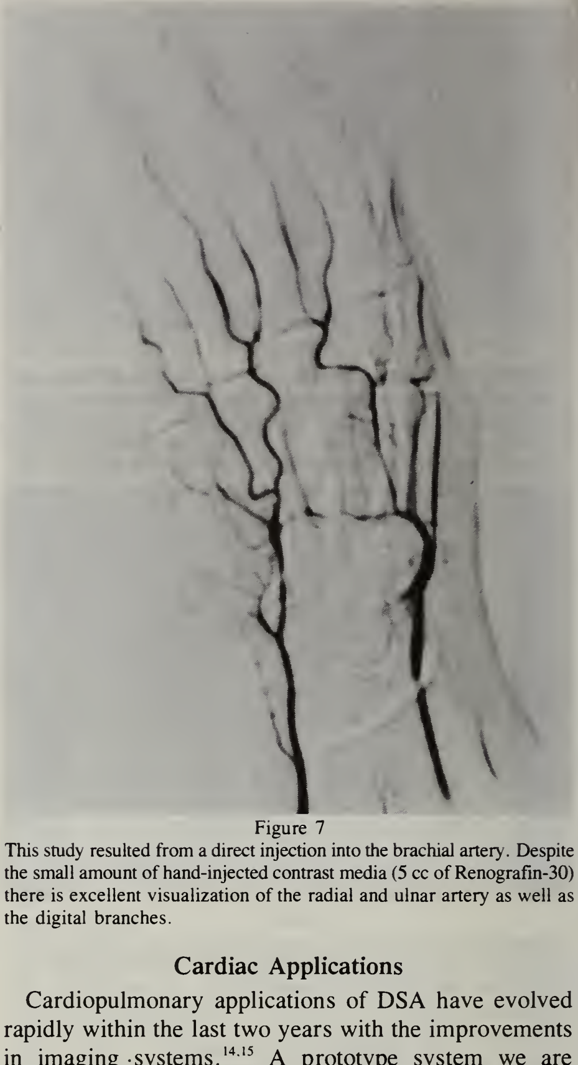

Figure 7
This study resulted from a direct injection into the brachial artery. Despite the small amount of hand-injected contrast media (5 cc of Renografin-30) there is excellent visualization of the radial and ulnar artery as well as the digital branches.

Cardiac Applications

Cardiopulmonary applications of DSA have evolved rapidly within the last two years with the improvements in imaging systems.[14,15] A prototype system we are evaluating is capable of EKG gated digital images at 30 frames per second. This data will be ultimately available in a high resolution 1024 x 1024 resolution matrix. These advances will surely enhance the cardiac potential of DSA. Already Higgans[16] has applied these techniques to left ventricular dimension analysis, providing data related to: ejection fraction, cardiac output and wall motion. An intriguing application currently under study is the evaluation of coronary artery bypass grafts using an intravenous approach. Using our prototype equipment, we have attempted studies in several such cases. While the quality of the examinations are still suboptimal and are not yet recommended for routine clinical use, we were able to demonstrate both patent and blocked coronary artery bypass grafts in the presence of fibrillation. Further efforts in this area is the subject of intense investigation by a number of centers.

Conclusion

Over the past two years, we have performed outpatient digital subtraction angiography on over 1,900 patients in both a modified fluoroscopic room with a 9-inch image intensifier and a state-of-the-art C-arm room with a 12-inch image intensifier. Our experience shows this technique to be both safe and cost effective.[17, 18] Approximately 90% of our studies have been diagnostic. There have been no serious complications. The performance of these studies on an outpatient basis is approximately one-third the amount usually associated with an inpatient arteriogram.[19, 20]

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Stress and the Heart—Behavioral Interaction and Plan for Strategy

STEPHEN T. SINATRA, M.D.

ABSTRACT—For centuries, psychological and behavioral factors have been known to influence disease. The powerful role of the mind in health and healing has long been recognized, and physicians have been particularly cognizant of the impact of emotional states influencing acute and chronic disease. The following communication is a representation of a lecture given by the author throughout many of the hospitals in Connecticut. The article discusses the role of emotional stress, suppressed feeling, behavioral interaction and cardiovascular disease. Type A coronary prone behavior is becoming an adaptive and frequently maladaptive behavioral response in a modern society faced with rapidly changing times. Research suggests that Type A behavior may be the missing link and perhaps the strongest predictor in the genesis of future coronary heart disease. Since many physicians themselves are prone to Type A behavior, it is particularly important for physicians to be aware of the manifestations of "Type A-ness." In the following article, behavioral manifestations of coronary heart disease are described with particular emphasis on the individual variability of one's physiological and psychological behavioral response to stress. The origin of Type A behavior is discussed. Some guidelines for detection and management are suggested, and a plan for behavioral strategy is advised.

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Although emotional stress has long been recognized by the physician as an intuitive belief in the etiology of coronary heart disease, sufficient data now exist that psychogenic stress is a major coronary risk factor.[1] Stress is frequently associated with rapidly progressive social change inducing an imbalance between the individual and the environment. With our society's competitive structure, environmental imbalances and rapidly changing social mores, modern man, by necessity, has developed behavioral patterns in response to an uncertain, unpredictable and threatening world. Twentieth century man has responded to external stress with a complex behavioral response composed of multiple variables affecting emotion, feeling and personality. Type A behavior, coronary prone behavior and narcissistic aggressive patterns have become contemporary man's means of coping with an uncertain changing environment.

Anxiety, illness, depression, fatigue, severe emotional and medical problems—these are all symptoms of adult stress and manifestations of coronary prone behavior which often has its origins in childhood.[2] Adults with Type A coronary prone behavior have twice the risk of myocardial infarction over their Type B counterparts.[3] They also exhibit more extensive coronary atherosclerosis, both at autopsy[4] and on angiographic evaluation.[5] One of the major characteristics of coronary prone Type A individuals is a sense of time urgency, competitiveness, desire to control events and easily provoked hostility.[6] Thus, they appear to be high-driving, aggressive, easily annoyed and competitive in their struggle to control events. When attempts to control are met with repeated failure, they act helpless and give up. The Type A behavior pattern, therefore, is a specific way of coping with stressful events in our external environment. Its etiology remains unclear. It may be that certain individuals during early developmental stages of life inherit a predisposition to perform and think rapidly. A subset of these individuals go on and learn to be competitive from family who hurry a child to achieve. Finally, another subset as they grow older, gets frustrated and hostile when others do things more slowly and interfere with their own goal attainment.[7] Others feel that a Type A individual creates a sense of urgency as a result of underlying panic. If the drive of a Type A person is concerned with control, the individual strives to break free because on some level he feels trapped.[8] Research in this developmental phenomenon of Type A behavior in childhood has identified certain behavior patterns that mirror the adult Type A coronary prone behavior pattern. Such behaviors as eating and talking fast, talking loud, being high-driven and diligent, characterize children who at early age demonstrate physiological evidence predictive of future cardiovascular events. Even in childhood, measurement of the Type A behavior pattern has demonstrated increased levels of cholesterol and blood pressure values.[9, 10] When adults, these Type A children may go on to develop self-destructive coronary prone behavior culminating in coronary heart disease. Since disease may be an ongoing process which frequently has its origin in childhood, the inappropriate coping styles and maladaptive behavior patterns may result in biochemical alterations which may eventually predispose individuals to pathological situations.[11] Of cardinal importance and perhaps the major theme in this communication is an individual's behavior response to stress. Although the inherent Type A behavior pattern is quite significant, one's physiological and psychological behavioral response to stress is of paramount importance and is perhaps the catalyst in the stress-distress cascade (Table 1) which may eventually culminate in illness. Several investigators, for instance, have demonstrated the independent variability and susceptibility of an individual's response to stress. Selye,[12] for instance, in describing the general adaptive syndrome revealed the importance and relevance of the stressor and stress response model. Wolff et al[13] demonstrated the effectiveness of defense and coping styles, in parents dealing with terminally ill children. In a previous study,[11] we demonstrated the significant impact of a positive self-image and "support" in an individual's response to stress. Moreover, it has been demonstrated that negative emotions, particularly fear and depression, may be associated with a significantly higher incidence of disease and is frequently seen in situations of recent bereavement.[14] Hence individuals will exhibit a difference in susceptibility to disease based upon their own feelings and their own characteristic response to various stressors.

Table 1
STRESS-DISTRESS CYCLE

1. External performance demands, challenges, stressors
2. Internal behavioral response—physiologic and psychologic
3. Biochemical alterations—neuroendocrine response
4. Optimal stress vs. distress
5. Adaptability vs. maladaptability
6. Pathological changes—illness

Accordingly, one has to consider the strong behavioral and emotional components of maladaptability frequently manifesting itself in the well-known traditional cardiovascular risk factors. The impact of neuroendocrine mechanisms in the acceleration of atherogenesis, for instance, has been demonstrated in experimental animal studies[15] and hypertension has been associated with internalized anger and rage and an increase in norepinephrine levels.[16] Multiple lipid studies have also demonstrated subsets of individuals prone to an increased lipemic response as a result of emotional[17] and/or occupational stress.[18] Maladaptive mechanisms such as smoking, overeating, overuse of alcohol and hypertension are frequently seen as an individual's maladaptive coping mechanism in response to chronic stress. Personality type, experience, adaptability and cultural factors may also determine why one individual responds to a stressful event by developing disease while another does not.[19] External stressors, feelings, personality and one's intrinsic behavioral response to stress are frequently observed as significant variables that may interact in the pathogenic process. Chronic stress may potentiate underlying structural disease and acute psychological arousal may actually precipitate overt attacks.[20] In one study, high levels of anxiety, depression and sleep deprivation were found in coronary patients[21] and in another study, the high incidence of myocardial infarction and sudden death was found in depressed individuals with recent changes in their psychological arousal.[22] Acute psychological arousal and active coping increase sympathetic activity and augment the discharge of catecholamines such as norepinephrine which may elevate blood pressure, enhance the rate of arterial damage and facilitate the occurrence of fatal cardiac arrhythmias.[1, 23, 24] With a shift to parasympathetic dominance, often associated with helplessness in giving up, there is severe depletion of norepinephrine.[25] One theory is that it is this abrupt shift between sympathetic and parasympathetic activity which may contribute to sudden unexpected cardiovascular disorders, including sudden cardiac death.[26] The chronic struggle to exert control over threats in the environment with a subsequent increase in sympathetic activity may result in maladaptive behaviors that cannot possibly succeed. This may result in cumulative, negative and physiological consequences as seen in the following example. A corporate executive, on his way up in the company, has found his expected promotion blocked due to company politics. It will come, but not so soon as he has anticipated. Meantime, his work goes on, pressured, but no more than usual. He has, however, begun to develop headaches and shortness of breath, both of which generally disappear on weekends. Life at home is pretty much the same; relationships are fine, if occasionally unsatisfactory. However, in the last month, he has had to buy a new car, pay towards his son's braces and try to understand his wife's need for increased self-fulfillment. It is now Saturday evening, our executive is unwinding from his time-pressured hectic week by having dinner in a local restaurant with his wife and another couple. Over cocktails and cigarettes, they laugh, sharing stories of family situations and job pressures. They order bottles of wine and enjoy a dinner high in lipid content. Later that evening, our corporate executive suffers a massive myocardial infarction.

This is a typical scenario—the scenario of sudden unexpected cardiac death. Generally, there are strong behavioral and psychological factors just preceding the event. Sudden death occurs more on Monday and Saturday and is related to either gearing up or gearing down.[27] The profile of the person typically affected is the middle-aged male who has recently ingested an alcoholic and free-fatty acid meal. He is a smoker, is psychologically hyperactive and is generally experiencing some acute stress. In all probability, he has a tendency towards hypertension and/or a tendency towards arrhythmia (Figure 1).

It is easy to look at this rather typical corporate executive and see that he has violated nearly all of the risk factors associated with heart disease. He has chosen to ignore the cost his body will pay for his life style. Generally, the question is "why?" Why does a person put so much strain on his body that ends in total collapse? The answer, complicated and relative, lies in perceived needs, unspoken fears, and a strong need to succeed according to external and societal standards. To even begin to alter these needs would be a lifelong nearly impossible task. For these individuals, the question is not so much "why" as "how." How can they maintain their goals, meet their needs and yet keep their bodies from paying too high a price. The answer is woven within the words "STRESS," a six letter word that has become a tapestry of why's and how's.

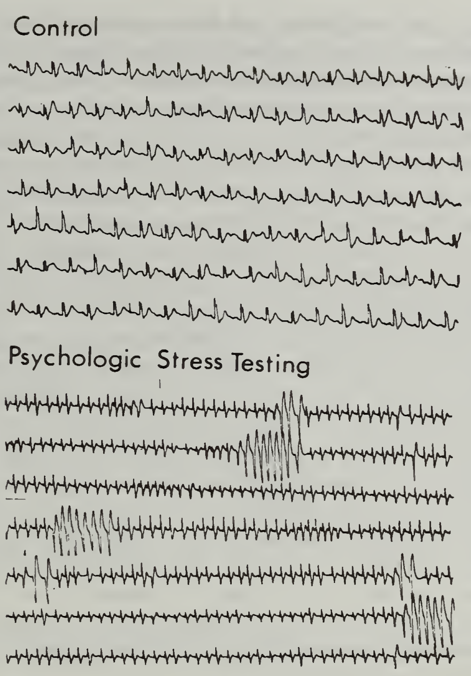

Figure 1
Ventricular tachycardia induced by psychologic stress testing (monitor leads). TOP, control tracing preceding test shows sinus rhythm at 65 beats/min. (During the preceding 24 hours of monitoring, no advanced grades were recorded.) BOTTOM, during psychologic stress testing, heart rate increased to 92 beats/min, and recurrent runs of supraventricular tachycardia and ventricular tachycardia occurred. *(With permission from Lown, et al: Roles of Psychologic Stress and Autonomic Nervous System Changes in Provocation of Ventricular Premature Complexes. Am J of Card 41:979-985, May 1978.)*

The world is filled with situations and happenings; some by their own very nature, are more important than others. Hunger and deprivation are unquestionably more important than a flat tire. Except for the individual who has to deal with one flattened tire and no jack. A failing grade should be eminently more important to a college coed than a broken fingernail except if she views her polished fingernails as a source of attractiveness. The flat tire and broken fingernail, then become external stressors in these person's lives. How they respond to these and other stressors will determine their bodies physiological reaction and ultimate health. A stressor is something to which special weight and significance has been attached. Stress is a resistance of the body and mind to those external stressors; it represents an individual's response to threat, demand, or change. Stress can be something as simple as a feeling of being overwhelmed—too much to do and not enough time to do it; it can be the lack of surrender—the inability to give into a situation with fear of losing control; or it can be the feeling of threat or uncertainty. Often a stressor cannot be changed or even controlled. What can be controlled, however, is the patient's behavioral response that develops due to an individual's response to the external stressor. When the promotion does not come, when the tire goes flat, when the fingernail breaks, the individual has only one of two choices—adapting or maladapting. He can adapt by "going with the flow," accepting situations or working to affect the change. Or, maladapting. He can prepare his body for viseral vascular readiness, either withdrawing into himself or pushing beyond normal expectations in an effort to make the stressor go away. Sometimes, this maladaptability is exhibited in coping styles that are unhealthy and inappropriate such as drug or alcohol abuse, overeating or overworking. These activities, in themselves take an enormous toll on the body.

Today's stressed individual cannot "fight or flee," an effective mechanism used by our ancestors. Within the confines of a sophisticated and demanding society, most people accept external stresses by putting their bodies in a chronic state of preparation. The chronic alarm reaction that develops is a harmful response in which the body continuously overdoses on its own cortisol and adrenalin.

When the body enters into this modern fight-flight response, the released catacholamines raise blood pressure, increase heart rate and breathing. If the body remains in this chronic alarm action for any length of time, the individual becomes prone to any of the stress produced conditions, ranging from aching neck muscles and headaches to ulcers, allergies, diminished sexual desire and perhaps cardiovascular disease.

The biochemical alterations that occur from the behavioral response to stress are powerful, and physicians have long been witness to both the physiological and psychological responses to stress. When these responses are inappropriate or ineffective, the individual develops "distress." When the person cannot find an appropriate adapting mechanism to a particular stressor, he, by necessity, maladapts. Pathological changes that occur in the body because of this maladapting and hormonal secretion can be long term and even permanent. (Table 1)

The corporate executive cited earlier is a perfect example of the individual who maladapts to stress that is out of his control. He overworks; he overeats; he smokes. All of these are behavioral reactions to, and manifestations of, stress. He is also doing grave harm to his body. In addition, because he is always reacting to stress and very seldom adapting to it, his body remains in a chronic state of visceral vascular readiness. It is no coincidence that eventually he suffers an unexpected cardiac event.

Much of the answer in dealing with stress lies, not in the stressors themselves, but in an individual's response to these stressors, i.e., his behavioral response and coping style. An important step in learning how to adapt is recognizing some of the situations that create stress. These can be lack of communication, unfulfilled expectations, retirement, death of a loved one, job pressures, hostile relationships, and particularly important, dwelling upon past events or imagined future ones. Dwelling on "what might have been" or how life will change with future imagined events may influence stress biochemicals. So often, a patient will tell his physician, "my life will work when I retire" or "my life is going to be O.K. when I get divorced" or "when I change my job, things will begin to change." These projections keep the body in a constant state of anticipation and the eventual reality of unfulfilled expectations has a devastating effect on the body. The key is to live for the moment, to deal with problems as they occur rather than put them off to some vague future time. Life is now, this is it; and any real change is not going to come because of a relocation, advancement or a retirement; it will come only through adjusting attitudes towards present circumstances and understanding that the burden of future happiness cannot be placed upon a single, anticipated event. However, because attitudes and behaviors are learned at an early age, they are often difficult to change. Rather than enhance coping, attitudes and beliefs can actually become a barrier. They create the "truth" to which the body must react. An employee says, "my boss always makes me feel inadequate." In truth, the boss does not make him feel inadequate; he does, however, serve to enhance the employee's already established attitudes about himself. The employee reacts by becoming tense and hostile whenever his boss is around. Changing jobs will not alleviate the problem; it will only surface again. The only way for the employee to change the situation is to develop positive attiudes about himself and his capabilities. A great deal of stress is actually the result of the individual upsetting himself, of reacting to a situation by saying "such and such has been done to me." In all actuality, nobody can make another person feel inadequate, unhappy, unloved or guilty. These feelings and insecuritites come from within and are accepted from outside sources only when the belief already exists. The immediate stress can be relieved if the person removes himself from the external situation that reflects these attitudes. The long term coping will only come when the individual begins to alter his own attitudes and beliefs about himself. This is the power of self-talk—a powerful coping skill.

This is where physicians come in. Today, more than ever, we are dealing with patients whose diseases are a result of mind and body and no longer capable of coping with external stressors. Over a period of time, the patient has lost his ability to adapt to the presence of the world; yet he is not able to remove himself from them. The result is illness. One of the greatest challenges for today's physician is to treat these illnesses by looking for the cause as much as for the treatment. Cause and cure are interrelated in such a way that total cure cannot be affected until the cause is determined and treated. This generally means that the patient and physician share in the healing process. Patients have the power to enhance healing; it is the role of the physician to stimulate that power. One of the most effective methods utilized by physicians in this healing partnership is that of listening. A powerful medicine, it has also become a modern day art form. When a physician listens in a non-hurried, non-judgmental manner, the patient unearths feelings about himself and his behavior, and begins to understand which actions become personally self-destructive. With some direction, the patient can try on new behaviors which may result in better coping and therefore, less stress. Because behavior is learned at a very early age, quick or drastic changes cannot be expected. Changes will be gradual and, in all possibility, there will be resistance from many patients who want the "quick pharmacological" cure. It will be up to the physician to point out, for instance, the causes of over-arousal which frequently result in biochemical alterations resulting in more susceptibility to illness and disease. (Table 2) It will be up to the physician to point out the cause and effect relationship between behavior and disease and urge the patient to adapt more effective coping mechanisms. A person with a Type A personality will probably not be able to shed the traits which have seen him successfully through life. But, with guidance from his physician, he can learn to be healthier Type A.

Table 2

CAUSES OF OVER-AROUSAL

1. People exerting excessive control over our lives
2. Unacceptable time pressures
3. Sleep deprivation
4. Increased frequency of life style events

Stress, and its resulting illnesses, occur when the body is no longer able to effectively cope. When the body, itself, has remainded too long in the chronic alarm stage. This happens most often when the patient is going through major lifestyle changes. Very often, the changes may have already taken place. The reactions, however, are still occurring. Too many lifestyles changes within a short time can trigger a bodily breakdown including a major cardiac event.[28] It is important for the physican to recognize this and not, unwittingly, add to the stress, by requiring even more adjustments for the sake of the patient's health. An example of this might be the person who has had frequent lifestyle changes and sees his physician for treatment and investigation of illness.

If the physician sees the signs of possible coronary insufficiency, he tells his patient to immediately give up smoking, lose weight and alter his diet. More lifestyle changes, perhaps too many at once. Before requiring more changes from his patient, it is essential that the physician encourage him to talk about his life in other ways, that he might better handle the stressors he is facing. Once effective coping mechanisms have been discussed, the physician can move slowly into the necessary medical requirements that also require a change in lifestyle. If at all possible, these should be implemented one at a time, leaving room for adjustment—smoking one month, diet the next. The objective is to keep the limits of stress and arousal within the patient's coping capabilities in order to avoid excessive biochemical stimulation.

There are no easy answers in dealing with the manifestations of stress. It is the result of external and internal pressures placed on individuals who live in a technical, sophisticated society—a society in which competition and financial status are held in high regard. Stress is a byproduct of progress and certainly, a life totally void of it would lack challenge, excitement or motivation. Some stress is necessary and even healthy. The important factor is to reduce the amount of unpleasant stressors and to learn techniques that allow for appropriate coping. (Table 3)

Table 3

BEHAVIORAL MANAGEMENT TECHNIQUES—COPING STRATEGY

1. Know yourself—"Listen to the body"
2. Learn to say "No,"recognize fatigue and remedy it
3. Stay fit with proper diet and exercise
4. Vacation and leisure time
5. Experience emotions without self analysis or editorialization
6. Lower arousal through muscle relaxation techniques—yoga, progressive relaxation, bioenergetics, etc.
7. Beware of negative "self-talk"and how much we upset ourselves, do not dwell on past and future events
8. Laugh and play
9. Reduce frequency of life style events
10. Cannot fight or flee—go with the flow

One important technique is to reduce the frequency of negative life style changes and another source of release is old-fashioned horse play. Exercise is extremely helpful, and the benefits of exercise were discussed in a previous communication in this Journal.[29] Still another technique is learning to express emotions; it is not weak to cry or show feeling—it is healthy, far healthier than the effects of internalized sadness or anger. And, of course, there is laugher, a medicine that has transcended time.[14]

If a person can contribute, however, unwittingly, to his own disease process, then he is also capable of triggering mechanisms in his mind and heal the body and keep it well. Channeled correctly, the emotions and reactions that hurt the body can also heal. The trick is to be able to look at something negative and find some positive force, no matter how small; to be able to laugh at yourself and not take everything quite so seriously, to be able to communicate honestly and not internalize personal work pressures and be able to reach out, love, and, in return, accept the sincere affection of others. These are the forces and positive emotions that heal. And these are the forces that create a vital and challenging role for today's physician, for he may find a way to unearth and mobilize these positive forces in patients who exhibit disease as a negative reaction to stress. The physician needs to carry his role another step beyond diagnosis and treatment; he must now accept an active role in responsibility in dealing with the cause of the illness. Only then can health truly be effective and well-being maintained. The physician needs to be supportive and noncoercive and acknowledge his patient's feelings and emotions without his own judgment and editorialization. The physician cannot take away the stress, past or present, in his patient's life, but he can provide the time and the space to explore with the patient the negative forces, as well as any destructive personality traits that have contributed to the illness. In this way, the patient and the physician become partners in the treatment and control of the disease. Both begin to share in the ongoing process of health rather than the treatment of disease.[30] Learning to cope takes practice and awareness. But as patient and physician learn to listen to the body, they will learn what is happening to it ... and why. The body will give a message and will almost always speak the truth.

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Human Pulmonary Dirofilariasis

Two Case Reports

M.M. DEREN, M.D. AND BRUCE FEINBERG, B.S.

Introduction

Dirofilaria immitis, the common dog heartworm, has been identified in the pulmonary nodules of two patients from the New London area. Current literature[1, 2] suggests an increasing incidence of solitary pulmonary nodules in humans secondary to this nematoid infection, which previously was thought found only in lower mammals, commonly the dog. On roentgenogram the lesion is a non-calcified "coin lesion"usually spherical, 1 to 3 cm. in diameter.[1] Because no reliable preoperative serologic tests exists, compounded with the possibility of misdiagnosing the infection as a carcinoma, the only known treatment is thoracotomy and resection of the lesion.[1,3]

Case Reports

Case Report 1: A 59-year-old white male was admitted with a diagnosis of coin lesion of the right lung found on routine chest x-ray (Figure 1 and 2). Chest x-ray two years previous was normal. The patient was asymptomatic but was a heavy smoker. Past, family, and social histories as well as review of systems were unremarkable. Physical examination demonstrated an increased AP diameter of the chest, but otherwise was normal.

Laboratory values showed a HCT of 49, a WBC of 7,100 with 4 monocytes, and 3 eosinophils. Chemistry profile was normal. A further chest x-ray and laminograms demonstrated a 2.3 cm. non-calcified mass in the middle lobe. Tumor was the primary consideration. Middle lobectomy was performed with an unremarkable post-operative course. Pathological evaluation revealed dirofilaria. This was confirmed by pathologic consultation from the Department of Pathology, Yale University School of Medicine.[4] Figure 3 demonstrates three portions of the nematode in an occluded vessel within the nodule and Figure 4 demonstrates a close-up of one portion of the parasite.

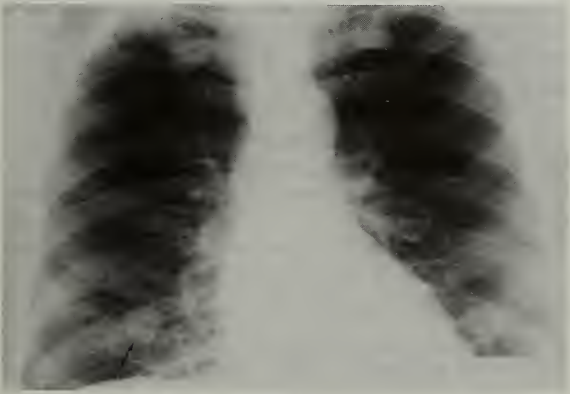

Figure 1

Case Report 2: A 57-year-old white male was admitted for a coin lesion of the left lobe of the lung found on routine x-ray. The patient was asymptomatic but smoked one pack of cigarettes per day for many years. Past, family, and social histories were non-contributory. Physical examination was unremarkable. Chest x-rays and laminograms demonstrated a 2 cm. lesion, suggesting an infiltrative growing mass lesion.

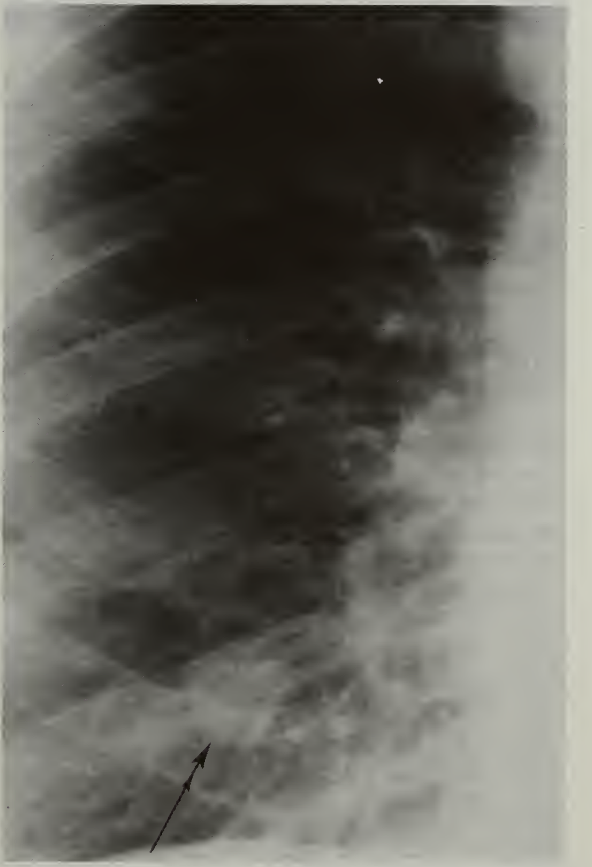

Figure 2

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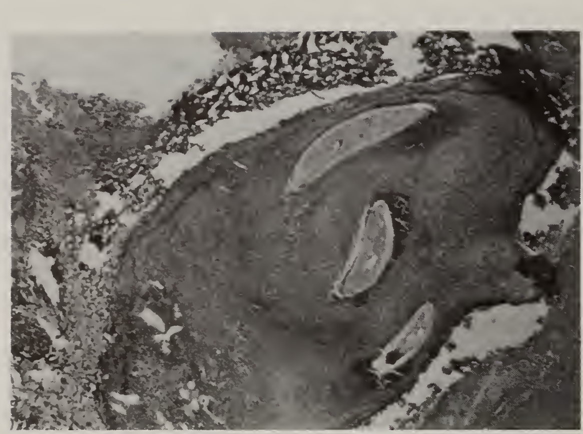

Figure 3

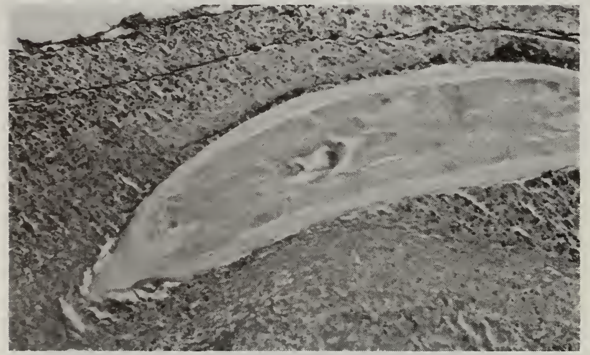

Figure 4

Laboratory values showed a HCT of 47.9, a WBC of 8,400 with 55 neutrophils, 1 eosinophil, 5 monocytes, 33 lymphocytes, and 6 atypical lymphocytes. Chemistry profile was normal. Exploratory thoracotomy was performed and the lesion of the lingula was wedge resected and found to be benign by frozen section. Post-operative course was unremarkable. Permanent pathologic evaluation, confirmed by consultation at the Department of Pathology, Yale University, School of Medicine,[5] demonstrated dirofilaria.

Discussion

D. immitis is one of several canine nematodes. Other natural definitive hosts, although less common, include the cat, fox, muskrat, wolf, otter, and sea lion.[3, 6] The adult nematode localizes in the right ventricle of the definitive host, where the female worm sheds several thousand microfilaria daily. These circulate in the peripheral blood where they may be transmitted to another host by a mosquito vector. Although not proven, it is assumed that man is also innoculated by an infected mosquito carrier.[3]

Mature *D. immitis* females are 25 to 30 cm. by 1 to 2 mm. with their male counterparts being between 12 to 18 cm. by 1 to 2 mm.[6] There is a thick multilayered cuticle, abundant somatic musculature, an intestine, and single (male) or paired (female) reproductive tubules.[6]

The human appears to be an accidental and unnatural host for the nematode.[6] The worm probably migrates to man's right ventricle, but dies before reaching sexual maturity. The necrotic worm is then carried to the pulmonary circulation where it impacts, allowing for thrombus formation.[6] No microfilaria have ever been observed in human peripheral blood.[3]

Clinically, the condition is generally asymptomatic. When symptoms do occur, the most common are chest pain, cough and hemoptysis.[6, 7] Eosinophilia is infrequent.[6] The lesion is usually discovered upon routine roentgenographic examination. There is no known long term complication from the infection.[1]

The lesion is usually a subpleural, well-defined spherical mass, consisting of a firm fibrous wall which surrounds a softer, central necrotic zone. The necrotic area contains a thrombosed pulmonary artery within which a single worm, often fragmented, is usually found.[3] The worm, however, often may be missed upon microscopic examination since the pathologist might trim it away due to its eccentric position within the nodule.[1]

We can expect to see a rise in human pulmonary dirofilarial infection secondary to an increase recently reported in primary host (canine) infection.[1] The geographic boundaries of canine infection are rapidly expanding in the U.S. and now include the midwestern states from the southern Mississippi Valley to the Great Lakes and Canada as well as the already documented eastern seaboard and Gulf States.[1] Hence, a knowledge of epidemiologic factors should prove important in the presumptive diagnosis of dirofilariasis.

Diagnostic evaluation of small coin lesions often focuses on neoplasms with thoracotomy and resection of the lesion being the treatment. Since the definitive diagnosis of dirofilariasis is at present limited to postoperative histopathologic examination,[3] it appears then, that in the absence of an appropriate and effective preoperative serologic test [2, 3] surgical removal of the lesion will remain as the only alternative.

Addendum: We would like to express our appreciation and thanks to Dr. Phillip Wade, Department of Surgery, Lawrence and Memorial Hospitals for the use of case #1, Dr. G.J. Walker Smith, Department of Pathology, Yale University and Drs. David Nelligan and Joaquin Dorantes, Department of Pathology, Lawrence and Memorial Hospitals.

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Important Advances in Clinical Medicine

Epitomes of Progress—Radiology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in radiology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in radiology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Radiology of the California Medical Association and the summaries were prepared under its direction.

Neonatal Abdominal Ultrasonography

The abdomen, pelvis, heart and head of a newborn infant are readily imaged with high-frequency small parts ultrasound equipment. Real-time ultrasonography equipment is portable, allowing rapid evaluation of a nonsedated fragile neonate in an intensive care nursery.

The most common abdominal masses in newborn infants are of renal origin. Ureteropelvic junction obstruction and resultant hydronephrosis, multicystic dysplastic kidneys, renal vein thrombosis and renal tumors comprise the bulk of these masses. A normal neonatal kidney has decreased renal sinus echogenicity, vis-à-vis an adult kidney, prominent medullary pyramids and an accentuated corticomedullary junction. Echogenicity of a newborn renal cortex is often greater than that of an adult and may equal or exceed that of adjacent liver or spleen. Ultrasound studies easily distinguish between renal masses and nonrenal masses. A multicystic dysplastic kidney has multiple renal cysts located in the region of the kidney, without evidence of a normal renal pelvis or renal parenchyma. Such an appearance is easily distinguished from the dilated fluid-filled pelvis and communicating calyces of a hydronephrotic kidney. The elongated, distended extrarenal pelvis in a ureteropelvic junction may simulate a dilated ureter and the distal ureterovesical junction should be imaged in all cases of hydronephrosis to better delineate the nature of the lesion. The kidney in cases of renal vein thrombosis is usually enlarged and has increased or decreased echogenicity and areas of parenchymal inhomogeneity. Thrombosis is often shown in the renal vein itself and Doppler flow analysis of renal vein patency may offer additional benefits in detecting renal vein thrombosis.

A normal neonatal adrenal gland is readily found using coronal scanning. The right gland is identified in 97% of neonates and the left in 83%. The neonatal adrenal gland is characterized by a thin echogenic core surrounded by a thick rim of sonolucency. The ability to detect adrenal hemorrhage and tumors in neonates has been well described.

The normal neonatal liver, venous anatomy both portal and hepatic and the gallbladder and biliary tract are easily visualized. Gallbladder length, width and width-to-length ratios are unreliable criteria for separating normal from pathologic gallbladders. Gallbladder sludge is a relatively nonspecific indicator of potential gallbladder disease and appears to be related to neonatal stress from any source. Gallbladder wall thickening and sludge resulting from severe neonatal illness may be visualized by ultrasound study for several weeks despite pronounced clinical improvement. Identification of a normal gallbladder and biliary tract in a jaundiced patient is highly suggestive of the diagnosis of transient jaundice of the neonatal period or neonatal hepatitis. Failure to show the gallbladder and biliary tract on two separate examinations done when a patient is fasting is highly suggestive of biliary atresia, a finding that can be con-

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firmed by technetium Tc 99m lidofenin (HIDA) radionuclide studies. A normal infant's common bile duct should measure 2 mm or less in diameter in the first three months of life. An internal common bile duct measuring more than 2 mm in diameter suggests a pathologic or physiologic obstruction. Congenital hepatic tumors including hemangioblastomas and hepatoblastomas can be imaged sonographically. Benign vascular tumors of the liver including hemangioendotheliomas and mesenchymal hamartomas present as complex hepatic masses associated with dilated abdominal aortic and venous structures.

About 15% of neonatal abdominal masses arise from the gastrointestinal tract. These include omental and mesenteric cysts and gastrointestinal tract duplications. The hypoechoic concentric muscular thickening of pyloric stenosis is easily diagnosed by ultrasonography. Gastrointestinal masses can be distinguished from retroperitoneal masses and free intraperitoneal fluid due to peritonitis or hemorrhage can also be detected.

Many additional applications include the use of ultrasound to define normal neonatal genitalia and imaging pelvic masses in a newborn. One can also use ultrasonography to detect tethering of the neonatal spinal cord and to locate the level of the distal pouch in evaluating cases of imperforate anus. Diagnostic applications of rapid, noninvasive, high-frequency ultrasonography in neonatal abdomens continue to increase.

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Nuclear Magnetic Resonance Imaging of the Whole Body

In the past year, the clinical evaluation of whole body nuclear magnetic resonance images has started at several centers in the United States. The technique measures the hydrogen density of a tissue and the effects of the molecular environment on the hydrogen. As a result, nuclear magnetic resonance provides cross-sectional images of the body with soft tissue contrast superior to that of x-ray computed tomography (CT). Spatial resolution is rapidly approaching that of CT and, in addition, there are no known hazards. Due to the static and varying magnetic fields and radio fields used, however, people with ferromagnetic or large metallic implants are presently excluded.

Because clinical evaluation has just begun, the actual clinical usefulness of whole body nuclear magnetic resonance imaging is unknown; it is showing good clinical potential in several areas. Because rapidly flowing blood causes blood vessels to be imaged as dark lumina, the vascular anatomy of the neck, medastinum and abdomen can be seen in great detail without the need for intravenously given contrast agents. This effect of blood flow plus the ability of the nuclear magnetic resonance imager to be gated from a patient's electrocardiogram enables gated images of the heart to be obtained throughout the cardiac cycle.

Nuclear magnetic resonance clearly images all the major intra-abdominal, retroperitoneal and pelvic organs. It is presently comparable but not superior to CT in identifying most of the organs. Only a few pathologic conditions such as hepatic neoplasms have been studied in detail, but nuclear magnetic resonance imaging appears to have the potential to provide at least as much information as is obtained by CT.

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Ultrasonic Evaluation of Neonatal Vascular Catheters

The abdominal aorta and its branches, the inferior vena cava, portal vein and hepatic veins are readily imaged in the abdomen of a neonatal infant using high-frequency ultrasonography. Umbilical catheters are commonly used in neonatal intensive care. Ultrasound location of these catheters is a noninvasive technique that involves no ionizing radiation and has no known detrimental side effects. Sonographic catheter location allows direct visualization of the aortic bifurcation and renal arteries, thereby allowing one to assess the position of the catheter tip relative to the vessels. Coronal and decubitus scans in both transverse and longitudinal projections allow accurate locating of arterial and venous catheters and can detect intravascular thrombus associated with catheter placement. Locating catheters can also be done at crib side, which is particularly valuable in a fragile newborn.

Umbilical vessel anatomy determines the distinctive course of umbilical catheters seen on both plain film radiographs and by ultrasound. The arterial catheter passes through either of the periumbilical arteries, travels inferiorly towards the ipsilateral internal iliac artery, then turns cephalad and passes retrograde into the common iliac artery and from there into the abdominal aorta. In our nursery, optimal arterial catheter tip placement is below the origin of the renal arteries and above the aortic bifurcation; however, in some nurseries the catheter tip is placed in the midthoracic aorta. The umbilical vein catheter travels superiorly in the midline as the umbilical vein courses through the falciform ligament to enter the liver where the umbilical vein joins the left portal vein. The catheter then crosses the portal vein to enter the ductus venosus and ascends through the ductus venosus to enter either the left or middle hepatic vein and from thence to enter the inferior vena cava on its way to the right atrium. Proper positioning of umbilical venous catheters should show the tip in the intrathoracic inferior vena cava or the right atrium.

About 17% of infants studied by the sonographic technique have had clinically evident signs of vascular compromise. Of these infants, ultrasound detected abnormal intravascular echoes or lack of radial pulsation in 10 of 12 or 83%. Abnormal echogenic foci, consistent with both thrombus and intimal dissections, were found. Ultrasonically detected abnormalities can be followed to resolution in infants. Typically the echogenic foci vanish and normal radial pulsation returns. The future evaluation of umbilical catheters within abdominal vessels can be augmented by combining Doppler analysis of flow within these vessels and high-frequency ultrasonic imaging.

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Ultrasonographic Evaluation of Fetuses

Because of technical improvements in both gray-scale and real-time ultrasound, prenatal ultrasonography has advanced far beyond its traditional roles of locating the placenta and determining fetal position, number and age. The fetus itself has come under increasing scrutiny. A variety of fetal anomalies can be consistently identified in utero. Recognition of many of these can dramatically alter patient management including the recent option of in utero interventional procedures.

The search for fetal anomalies with ultrasonography is carried out in two distinct patient groups. In the first group, the fetus is examined because of a genetic or familial history of a heritable disorder or an incidentally discovered risk factor such as an elevated amniotic fluid α-fetoprotein level. In these patients the prevalence of abnormality is high and an ultrasonographer knows which abnormalities may be present.

The second group includes those in whom a fetal abnormality is found serendipitously while the patient is being scanned for an obstetric indication, such as a discrepancy of size versus dates. In these patients the prevalence of anomalies is low. There is no genetic history of which abnormalities could conceivably be present. In such instances it is important not only to identify but to accurately characterize the lesion. For example, one should distinguish hydranencephaly from hydrocephaly; the prognostic implication is obvious. Accurately defined anomalies can alter the mode of delivery such as in cases of conjoined twins or a large sacral teratoma. The detection of such abnormalities as bilateral hydronephrosis, immune hydrops fetalis or hydrocephalus often affects the timing of delivery because such fetuses may be cared for more appropriately in a neonatal intensive care nursery than in their mother's womb. In addition, such lesions as posterior urethral valves and hydrocephalus can be diagnosed ultrasonographically and potentially treated in utero.

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Percutaneous Drainage of Abdominal Fluid Collections

A localized fluid collection in a critically ill patient who has a clinical diagnosis of abdominal abscess following a surgical procedure or an injury would have required surgical intervention in previous years, both for diagnosis and for drainage. Now in many instances these lesions may be percutaneously aspirated for a diagnosis and percutaneously drained for treatment by an interventional radiologist.

Locating a suspected intra-abdominal abscess is usually done by either sonography or computed tomography. These cross-sectional imaging techniques allow intraorgan, extraorgan and extra-alimentary fluid collections to be imaged both with precision and accuracy and in a rapid and noninvasive manner. Using these techniques, a safe percutaneous access to the fluid collection that avoids bowel, unaffected solid viscera and vessels can be planned. After finding the collection, an 18- or 20-gauge needle is placed in the fluid collection and a diagnostic aspirate is obtained. If the collection is unmistakably pus or infectious as noted by a Gram's stain, then a percutaneous catheter can be inserted to allow for continuous drainage. Appropriate antibiotics can be selected on the basis of results of a Gram's stain while results of cultures are pending. The catheter is connected to a closed-bag drainage system until drainage is completed. Noninfectious collections either may be aspirated through the needle or, if they are very large, a catheter may be inserted to allow for complete drainage over a one- to two-day period.

These drainage procedures are done using local anesthesia and minimal premedication. They are well tolerated by patients. Patients avoid the risk of a major operation and anesthesia. Hospital stay, hospital costs and nursing care are reduced for these patients. Morbidity and recurrence of drained abscesses are less frequent than in those patients having surgical drainage.

All patients should have a surgical consultation because a complication or inadequate drainage may necessitate a surgical procedure. Contraindications include coagulation problems, an unsafe percutaneous route and some multiloculated collections that would require placing multiple catheters. Major complications include sepsis, enteric fistulas and laceration of blood vessels.

The therapeutic success rate of percutaneous abscess drainage has been as high as 90%. Percutaneous abscess drainage should be considered as a therapeutic approach when treating a patient with possible intraabdominal abscess and radiographic evidence of intraabdominal fluid collection.

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Needle Biopsy

Recent advances in radiology, along with the technologic development of the "skinny" Chiba needle, have contributed to the current acceptance of the radiologically guided percutaneous needle biopsy. Cystic or solid lesions suspected of being malignant tumor, abscess or hematoma can be so diagnosed, thereby precluding the morbidity of an exploratory laparotomy. This procedure is particularly helpful when the likely diagnosis is a surgically noncurable malignancy or the patient is severely ill and a poor surgical candidate.

The Chiba needle is a 22-gauge thin-walled flexible steel needle with a 30-degree noncutting bevel and an inner fitted stylet. It and other needles similarly developed can generally yield enough aspirate for cytologic diagnosis.

Large lesions can be readily aspirated using either ultrasound (in the abdomen and pelvis) or fluoroscopy (in the chest). Smaller (2 cm or less) lesions or those near a vital organ can be reached with the guidance of computed tomography (CT). The three-dimensional aspects of ultrasound and CT enable the optimal path for needle placement to be selected, especially when the most direct path would involve passage through a vital organ. Computed measurement will indicate the desired depth of needle placement and angle of introduction.

As several specimens are often obtained, a second needle may be placed alongside the initially placed needle, using it as a guide. With this method reimaging of subsequent needle placements is often not necessary.

Aspirates obtained are immediately examined by an experienced cytologist—an absolutely vital step to this procedure. If samples are inadequate, the needle can be readjusted appropriately. "Failed" aspirates are often due to samples being taken from the necrotic center of a lesion.

Needle biopsy with the thin-walled flexible needles has proved to be a safe, quick and accurate method for defining the cause of chest, abdominal and pelvic masses. It may often obviate a surgical procedure and assist clinicians in an expedient manner in determining the most appropriate therapy.

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Vascular Occlusive Therapy

Vessels can be occluded for therapeutic purposes by using intravascular techniques. With these techniques angiographic catheter systems are used to deliver emboli or vasoconstrictors to the desired location. Among the situations that may be amenable to this form of treatment are arteriovenous malformations and fistulae, vascular tumors, vascular injuries, organ ablation and hemorrhaging.

Advantages of this type of therapy include decreased morbidity when compared with surgical alternatives and prompt application. At the time of initial diagnostic angiography, if a lesion is found it can be treated at the same sitting. In some cases the anatomic location of a lesion or a patient's clinical state makes surgical management impossible or unacceptably hazardous; vascular occlusion may be effective in such cases. It can also be used as an adjunct to surgical or medical care. Decreasing the vascularity of tumors or vascular malformations can make a surgical procedure easier in some cases. Hemorrhaging from unresectable tumors, the gastrointestinal tract and vascular injuries can be controlled.

A disadvantage of vascular occlusive therapy is that previous angiographic experience with catheter manipulations is necessary unless the vessels to be occluded are entered by direct surgical exposure. These techniques also carry more risk than routine angiography and risk versus benefit should be carefully weighed in each case. In the hands of physicians who have committed themselves to mastering these techniques the complication rates are low.

Complications that can occur include unwanted infarction or ischemia of normal tissue, pain following the procedure—which is usually transient—and infection. Other complications are inherent risks in angiography, such as allergy to contrast agents, bleeding at the vascular access site and so on.

Many agents are used to induce occlusion. They can be grouped broadly into the following four categories: particulate emboli, mechanical devices, solidifying liquids and vasoconstrictor drugs. The particulate emboli include the most choices. The first decision to be made is whether a temporary or a permanent occlusion is desired. If temporary occlusion is desired resorbable surgical sponge particles such as Gelfoam may be sufficient. For permanent occlusion we have used polyvinyl alcohol foam particles or silastic beads. When larger vessels are to be occluded a mechanical device may be necessary. This includes inflatable and detachable balloons and metal spring or coil devices such as the Gianturco coil. Most of the balloon catheter systems and solidifying liquids are still investigational. The vasoconstrictor drug used most often is vasopressin and it is used primarily for the control of gastrointestinal bleeding.

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Interventional Biliary Radiology

During the past decade significant advances have been made in radiologic procedures involving the biliary tract. In 1973 Burhenne described nonoperative removal of retained gallstones from the common bile duct. This is now the procedure of choice for removing postoperatively retained stones. Extracting retained stones is easier in relatively thin patients, when the drainage tract is short and straight and when the T tube is large, preferably Nos. 14 to 16 French.

Following cholecystectomy and T-tube placement, four to six weeks are allowed to pass for development of the T-tube tract. T-tube cholangiography is again done to confirm the presence and determine the location and number of stones. The T-tube is removed and a steerable catheter is promptly inserted in the T-tube tract. Fluoroscopy is used for guidance. The stone-retrieval basket is placed through the larger caliber steerable catheter and the stone is engaged in the basket and then extracted. Single or multiple stones can be removed in this fashion. If stones are too large to be removed via the T-tube tract, they can be broken into smaller, more easily extractable fragments and sometimes even flushed into the duodenum.

Some authors, such as Katzen, recommend that patients be given a broad-spectrum antibiotic such as ampicillin, 1 gram by mouth four times a day, one day before and until two to three days following the procedure, if done on an outpatient basis.

Percutaneous transhepatic cholangiography is now a well-established procedure for delineating the anatomy of the biliary tree in patients who have suspected biliary obstruction. Percutaneous decompression of the biliary system by means of a special catheter is an extension of the diagnostic percutaneous cholangiogram. This is done by placing a sheathed needle into the liver and positioning the tip into a dilated biliary radical. This catheter is placed in the biliary tree under fluoroscopic guidance while contrast material from the diagnostic cholangiogram is still in the biliary tree. A guide wire is inserted through the sheath and advanced beyond the site of obstruction. By manipulating the guide wire it can usually be made to traverse the obstruction. A specially designed Ring or pigtail catheter is then placed over the wire so that its tip lies in the duodenum. The pigtail shape serves to anchor the catheter in the duodenum and to minimize the risk of inadvertent removal. The bile enters side holes in the portion of the catheter above the obstruction and can flow through the catheter into the duodenum.

Considerable reduction in serum bilirubin level is effected in most patients. Biliary stent placement can help relieve pruritus caused by pronounced hyperbilirubinemia. Biliary decompression can also help reduce the risk of infection present in an obstructed biliary system. Biliary stent placement may effect palliation, without surgical intervention, for patients suffering from inoperable carcinoma of the pancreas or biliary tract.

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Digital Subtraction Angiography

Digital subtraction angiography couples a digital computer to a conventional x-ray fluoroscope to augment the visualization of blood vessels, using standard radiographic contrast media. Whereas it has been used in conjunction with selective catheter arteriography for enhanced visualization of vascular and neoplastic lesions, the enthusiasm for this procedure results from its ability, by means of intravenously given contrast agents, to visualize lesions in blood vessels.

Digital subtraction angiography requires the intravenous delivery of 20 to 40 ml of contrast agent over one to three seconds. This rapid delivery of contrast agent requires the placement of a 16-gauge needle in the antecubital vein, or passing a small No. 5 French catheter percutaneously from the antecubital or femoral vein into the superior or inferior vena cava. With these venous injections, some method of computer enhancement of the x-ray images is required to render the arterial structures visible. Typically a subtraction scheme is used—that is, images obtained before the injection of contrast are subtracted from those obtained after the injection of contrast. This *temporal subtraction* gives excellent visualization of extracranial carotid arteries, thoracic and abdominal aorta, renal arteries and peripheral vascular arteries. An important requirement for this temporal subtraction to be effective is that there be no voluntary or involuntary subject motion between the preinjection and postinjection images. In about 20% of the patients, the motion effects are disturbing enough that the information obtained is incomplete. Other situations producing inadequate digital subtraction angiography studies include poor cardiac output, inadequate venous access or inability to define a lesion exactly due to the problems of superimposition of other blood vessels. Overall, this examination technique is successful in 70% to 80% of patients. A number of correlative studies comparing it with standard catheter arteriography have shown that for the extracranial carotid, aorta, renal and peripheral arteries, a technically satisfactory digital subtraction angiography examination provides acceptable diagnostic information.

This technique has been extensively evaluated clinically at a number of centers. It has found a role in the evaluation of extracranial carotid occlusive disease, screening of asymptomatic carotid bruits, evaluation and detection of renal vascular hypertension, evaluation of bypass graft patency and detection and evaluation of thoracic and abdominal aneurysms. Its use for pulmonary arteriography is somewhat controversial. The examination is definitely useful, however, for showing major central pulmonary emboli, but its role in detecting more peripheral emboli is uncertain. It has also been used satisfactory in children. For cardiac applications, it has been used for evaluating left ventricular function. The results of using it for detecting coronary artery bypass graft patency have not been particularly rewarding, and for coronary arteriography it remains an important, but as yet unreached, goal.

Digital subtraction angiography is an invasive examination. Its appeal relates to the opportunity for outpatient arteriography, reduced patient risk by eliminating selective arterial catheterization and improved patient comfort. Much of the discomfort that occurs through the injection of contrast media selectively in arteries is reduced or eliminated through the intravenous route.

On the other hand, substantial amounts of contrast media are used for the digital subtraction angiography examination and the direct systemic effects, as well as the potential allergic effects of the use of the media, must be balanced against the clinical indications for the examination.

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High-Resolution Computed Tomography of the Temporal Bones

The high spatial resolution of computed tomography (CT), particularly with sectional or target imaging, is ideal for evaluating the temporal bones. A preliminary digital radiograph is taken and by using a cursor for locating, a series of thin (1.0 to 2.0 mm) scans is taken through the petrous temporal bones. The horizontal or axial plane is usually used. When possible, direct coronal scans can also be done with a patient's head hyperextended in the supine or prone positions. Target bone reconstruction is used for maximum spatial resolution to enhance bony detail.

Traumatic hemorrhage into the air-containing cavities of the temporal bone is recognized better by CT than by conventional pleuridirectional tomography. Opacification with or without fluid levels is discernible within the mastoid air cells or tympanic cavity.

The common tympanolabyrinthine or purely labyrinthine fractures of the temporal bone are vertical plane fractures. Axial CT sections are ideal for evaluating vertical fractures. The supine position is comfortable for a patient and the procedure can be done in emergency situations, even with polytraumatized patients. The CT examination can also provide information on traumatic lesions of the temporomandibular joint, the mandibular condyle or the base of the skull.

In patients with chronic otitis media, CT will show bony modifications such as bony sclerosis, hypopneumatization of the air cells or bony erosion. Demineralization or osteitic erosion of the ossicles, with or without displacement of the ossicles, may be detected in cases of cholesteatoma. CT in the axial plane is the best way to show a labyrinthine fistula of the lateral semicircular canal, which may be difficult to diagnose by conventional pleuridirectional tomography. Because of its superior density resolution, CT is useful in evaluating postoperative cholesteatomas when traditional tomographic landmarks such as the attic wall have been removed.

Thin-section CT is used to evaluate modifications of the cochlea in patients with labyrinthine otosclerosis. In addition, the scanner can be used to locate materials used in ossiculoplasties such as a stapes prosthesis.

Agenesis or hypoplasia of the external auditory canal or malformations of the tympanic cavity and ossicles can be shown by computed tomography. For inner ear malformations, axial CT is ideal for evaluating the cochlea when searching for a Mondini malformation. Complex malformations can be similarly studied to document dilatation of the vestibular aqueduct, the semicircular canals or the vestibule. The addition of intrathecal metrizamide with CT cisternography may help to show a fistula or a dehiscence of the fundus of the internal auditory canal in patients who have recurrent episodes of meningitis with cerebrospinal fluid otorrhea.

When tumors of the ear or temporal bone are suspected, CT should be done before and after intravenous injections of contrast material. CT, with its superior soft tissue detail, can more accurately determine the extent of disease in comparison to previous radiographic techniques such as plain films, pleuridirectional tomography and vascular studies. Not only is CT a significantly improved method of assessing the extent of these tumors preoperatively, but it is also useful in detecting tumor recurrence.

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The Role of Computed Tomography for Evaluating Temporomandibular Joints

High-resolution x-ray computed tomography (CT) is a useful new radiographic method for evaluating the temporomandibular joints. For most exquisite detail, thin-section (1 to 2 mm) axial dynamic scanning with maximum milliampere seconds and 0.5 to 1 mm overlapping is done so that motion-free, vertically reformatted images may be made. It is helpful to reconstruct images with both soft tissue and bone detail algorithms.

When we studied more than 50 patients, the method was particularly useful in two categories of patients: those with chronic joint pain and dysfunction and those suffering head and facial trauma. As in the case of the intervertebral disc, the fibrocartilaginous temporomandibular joint meniscus may be visualized when dislocated. If the meniscus is macerated, the joint space may be severely narrowed. The accuracy of computed tomography for directly visualizing dislocated meniscus is about 80% in our experience.

Often unexpected injuries accompany facial and head trauma. CT has been particularly useful in discovering temporal fractures that extend onto the temporomandibular joint articular surface, for follow-up of cases of condylar and neck fractures and for problems of reduced opening, as with bony and soft tissue ankyloses.

Joseph R. Thompson, M.D.

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Nuclear Magnetic Resonance Imaging of the Central Nervous System

The potential of nuclear magnetic resonance imaging of the central nervous system has been reported in many recent articles. The rapid development of this technology, however, has resulted in confusion concerning its clinical applications for evaluating neurologic alterations. Definition of its future role is further complicated by the lack of standardization of both the imaging hardware and the techniques of signal acquisition. Preliminary experience suggests that the technique is superior to computed tomography (CT) in detecting some disease processes and complementary to CT for evaluating others.

The sensitivity of nuclear magnetic resonance imaging to alterations in tissue characteristics is most evident for multiple sclerosis. The lesions of multiple sclerosis are shown as high-intensity foci with spin echo techniques. Inversion recovery images depict the lesions as areas of low signal intensity. Nuclear magnetic resonance spin echo images defined all of the lesions seen on the corresponding CT scans and many more that were not evident on CT.

This type of imaging may be done in the sagittal and coronal planes directly, in addition to the conventional axial tomographic plane. The soft tissue contrast realized is superior to CT, and in addition there is the notable absence of beam-hardening artifacts due to bone. These factors make this imaging technique ideally suited for evaluating the posterior fossa and also the spinal cord, where pathologic alterations such as tumors or syrinx cavities may be shown without intrathecal contrast.

Areas of infarction are defined by both CT and nuclear magnetic resonance; the latter modality, however, shows more extensive tissue involvement in both acute and subacute lesions. The characterization of an infarct as ischemic or hemorrhagic is facilitated by calculating nuclear magnetic resonance relaxation times.

Tumors are seen with both CT and nuclear magnetic resonance, but the latter is more sensitive because it has superior contrast resolution. In addition, it requires neither ionizing radiation nor iodinated contrast material to detect pathologic alterations. The potential characterization of tumors by their tissue relaxation times will require additional clinical experience and research.

Vascular anatomy is exquisitely defined by nuclear magnetic resonance images without contrast agents. Variations of the signal intensity of flowing blood are produced by alterations of the instrument parameters. The technique's ability to quantify blood flow is currently under extensive investigation.

The full potential of nuclear magnetic resonance as imaging technique has yet to be elucidated. However, the superiority of this new technique to CT in delineating some pathologic alterations of the central nervous system is already apparent.

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Radiotherapy for Prostatic Carcinoma

High-dose ionizing radiation is effective in controlling and potentially curing localized carcinoma of the prostate. In addition, irradiation can provide excellent palliation of symptoms in advanced disease. Programs currently using irradiation for treating early adenocarcinoma of the prostate gland can be divided into the following three basic plans, as outlined under stages B and C_1 (the advantage of one treatment plan over the others has not been established):

Stages B and C_1

1. External-beam radiation only.
2. Pelvic lymphadenectomy combined with radioisotope implant.
3. Pelvic lymphadenectomy, radioisotope implant and external-beam radiation.

A fourth treatment option that does not include irradiation is prostatectomy, which is usually limited to patients with small, low-grade lesions not involving the capsule and confined to one lobe of the prostate.

Stage A_2

All of the treatment options noted for stages B and C are used, although radioisotope implants are less frequently done.

Stage A_1

All of the treatment options noted above have been used as well as others. Close observation only is often suggested for patients having favorable prognostic factors.

Selecting the appropriate treatment is a multidisciplinary task for a team of oncologically trained and experienced physicians representing each modality involved in a patient's evaluation and therapy. Treatment planning must include consideration of major prognostic factors—that is, the extent of the primary lesion, the histologic grade (Gleason's score) and the extent of lymph node involvement. The patient's own desires must also be considered.

The external-beam option has been described by Bagshaw, who reported the results of using external-beam radiation for the treatment of 351 patients at Stanford University (Stanford, California) who had tumors confined to the prostate (nominal stage B or T_1). The actuarial survival rate was 78% at 5 years, 57% at 10 years and 39% at 15 years. In the same study, 310 patients with extracapsular extension (nominal stage C or T_2 and T_3) were noted to have an actuarial survival rate of 59% at 5 years, 39.5% at 10 years and 30% at 15 years. Patients treated before 1973 received radiation to the region of the prostrate only, and after 1973 patients believed to be at significant risk for lymph node metastasis received radiation to extended fields encompassing the pelvic nodes.

Relating to the second treatment option, Grossman and co-workers published their analysis of the first 100 patients at Memorial Sloan-Kettering Cancer Center (New York, New York) with stages B and C disease treated by means of bilateral pelvic lymphadenectomy and retropubic implantation of iodine 125 seeds. For 53 patients having disease limited to the prostate (stage B_1, B_2 or B_3), the five-year crude survival rate was 89%; the five-year disease-free survival rate was 60%. The early stage B lesion—that is, tumor confined to one lobe of the prostate gland—resulted in a 95% five-year crude survival rate and a 67% five-year disease-free survival rate. In all, 34 patients with extracapsular extension (stages C_1, C_2 or C_3) undergoing similar treatment were reported to have a five-year survival rate of 79% and a disease-free interval of 23%.

Guerriero and colleagues from Baylor College of Medicine (Houston, Texas) reported their results with the combined use of lymphadenectomy, interstitial implants using gold 198 seeds and external-beam radiation, which represents the third treatment option. The five- to ten-year crude survival rate for 33 stage B patients was 91%; the disease-free rate was 52%. In all, 20 stage C_1

patients were reported to have an 80% five- to ten-year crude survival rate and a 65% disease-free rate.

Severe irradiation complications are generally reported to involve less than 5% of patients and are usually limited to procitits, cystitis, urethral sticture, rectal stenosis and, rarely, small bowel obstruction.

Impotence following irradiation is reported to occur in from 2% to 30% of patients, suggesting in part the inherent difficulty in obtaining information regarding this problem.

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Percutaneous Transluminal Angioplasty in Peripheral Vascular Disease

The dilating balloon catheter developed by Grüntzig in 1976 greatly expanded the role of percutaneous transluminal angioplasty in the management of peripheral vascular disease. Unlike the coaxial dilating catheters originally introduced by Dotter and Jenkins in 1964, balloon catheters are flexible enough to allow dilatation of branch vessels and vessels at a great distance from the puncture site. In addition, balloons allow dilatation of stenotic lesions in large vessels, such as the iliac arteries, to a considerably larger luminal diameter. When compared with surgical treatment of peripheral occlusive disease, balloon catheter angioplasty is less expensive, less uncomfortable and has a lower risk and a much shorter convalescence. Treatment can be easily repeated, if needed, because access to the lesion is not impaired by postoperative scarring. Percutaneous transluminal angioplasty can be used safely in patients for whom a surgical procedure would carry a prohibitively high risk. Finally, if the procedure is unsuccessful, it rarely complicates or alters a subsequent surgical procedure. These advantages have led to a rapid growth in the use of percutaneous angioplasty: Dotter estimates that as many as 30,000 were done in the United States during the past year.

Several series have reported successful application of the technique in the treatment of iliac and femoral occlusive disease. Our initial success rates for iliac dilatation have been about 95% and three-year patency rates about 80%. Three-year patency rates for iliac lesions less than 2 cm in length have been about 86%, which is comparable to those of aortofemoral bypass grafting. Initial success rates for femoral-popliteal dilatation have been about 85% and three-year patency rates about 70%. Three-year patency rates for femoralpopliteal lesions less than 8 cm in length have been about 83%, which is comparable to the best results reported for femoral-popliteal bypass grafting using autogenous vein grafts and higher than those reported using synthetic grafts. Intimal hyperplasia developing within venous bypass grafts and at surgical anastomoses has proved responsive to percutaneous dilatation, and percutaneous transluminal angioplasty has prolonged the patency of the bypass grafts in this setting. The death rate directly attributable to this procedure has been about 0.4%, very much less than the 4% average mortality reported for femoral-popliteal surgical procedures. The morbidity rate has been about 5%, including hematoma (1%), clinically significant embolization (1%) and vessel thrombosis following dilatation (3%). The last rarely affects later surgical management.

When choosing the proper therapy for an individual patient, one should take into account the location, appearance and natural history of the lesions, the state of health and age of the patient and the severity of symptoms. This requires that an angiographer have a thorough clinical knowledge of peripheral vascular disease, including the limitations and hazards of each therapeutic option, as well as its proper application and chances for success. Great expertise in angiographic technique may be needed for safe passage of catheters through diseased or completely occluded arteries. Complete cooperation between radiologists and vascular surgeons is imperative if patients are to receive the best possible care. When these conditions are met, percutaneous transluminal angioplasty can be a useful tool in the treatment of many patients with obstructive peripheral vascular disease.

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Percutaneous Catheter Drainage of Abscesses

Advances in ultrasonography, computed tomography (CT) and the radiologic understanding of abdominal anatomy, coupled with catheter techniques, have significantly altered the current approach to intraabdominal abscesses. Immediate detection by cross-sectional imaging, diagnostic aspiration with fine, 22-gauge needles and subsequent percutaneous placement of drainage catheters is now well accepted and often the preferred therapy. The expanded role of an interventional radiologist in day-to-day ward care of patients is a concomitant outgrowth of the procedure.

Numerous studies have ascertained the prominent role of ultrasound and especially CT for accurately detecting abscesses. Under guidance by these techniques, aspiration and immediate Gram's stain establish the diagnosis of abscess and allow the institution of appropriate antibiotics. Candidates for percutaneous abscess drainage most frequently have pyogenic abscesses. Those with "sterile" abscesses (patients receiving antibiotics on a long-term basis), infected necrotic tumors, large amebic abscesses, hematomas and bile collections are all treated by similar techniques; the duration of catheter drainage is usually shorter, however. Puncture of a suspected *Echinococcus* cyst is always avoided.

The most important aspect of percutaneous abscess drainage is determining a safe entry route. Abscesses abutting the parietal peritoneum have the easiest access. If computed tomography shows an unobstructed pathway to the abscess, deeper collections may be drained. Overlying viscera, bowel, large vessels and sterile cavities are avoided in placing the catheter. The idea is not to harm other structures or spread infection. Interloop abscesses and those in the pancreatic head region are the most difficult to reach.

The technique of percutaneous abscess drainage involves direct trocar insertion or guide-wire exchange (Seldinger technique). The catheter may be placed under computed tomography, ultrasound, at fluoroscopy or by a combination of these. Abscess morphology, operator preference, modality availability and time constraints govern these decisions. In the evolution of percutaneous abscess drainage, a host of catheters has been used. Recently, specifically designed catheters with large holes, sump designs and facilitated insertion devices have become popular.

Catheter aftercare often determines the outcome of the procedure. As with surgical therapy, irrigation is a major component. Sequential sinograms are the usual mode of follow-up and record cavity shrinkage and obliteration. Patients responding poorly will have follow-up computed tomography or ultrasound and sinography to search for synchronous abscesses, loculations or fistulae.

Results of percutaneous abscess drainage support its prominent role as an alternative to surgical therapy and often as the procedure of choice. A complete cure with avoidance of laparotomy and general anesthesia has been reported in 75% to 95%. When treatment failures occur, patients may still undergo operation. For critically ill patients, a temporizing percutaneous drainage makes them more fit for a surgical procedure. Complications occur in 5% to 10% of patients. Recurrences indicate an underlying abnormal communication, such as an enteric fistula, anastomotic leak or pancreatic duct communication.

No controlled study comparing surgical and percutaneous drainage has yet been done. Inherent differences and problems for this type of study involve selectivity of cases in drainage; many patients undergoing percutaneous abscess drainage, however, are frequently quite debilitated and critical.

New procedures as outgrowths of percutaneous abscess drainage are developing. These include percutaneous drainage of loculated empyemas after failure of chest tube therapy, pancreatic pseudocyst drainage, pericardial drainage and percutaneous cholecystostomy. Tried and proved surgical dicta are adhered to whenever possible, as with conventional percutaneous abscess drainage. Early results are promising, but await further experience.

Eric vanSonnenberg, M.D.

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Neurosonography in the Operating Room

In the past, neurosurgeons have had many complicated procedures with which to identify the nature and position of an intracranial pathologic condition, which include angiography, computed tomography and nuclear medicine. Even with these sophisticated techniques, however, at the time of a surgical procedure after the surgically created cranial defects have been made, the dura reflected and the cortex of the brain exposed, the neurosurgeons have had to reply on their expertise and experience to define where to proceed in a dissection. They have not had a tool at the time of the surgical procedure to locate an intracranial lesion. Ultrasonography now enables them to actually define an intracranial lesion intraoperatively; to characterize it as solid, cystic or complex; to determine its size and location from the surface and its relationship to adjacent anatomy, and to detect pulsatility. This information is gained almost instantaneously when the transducer is gently placed on the cortical surface. Most pathologic lesions are discrete and clearly distinguishable from adjacent brain tissue and are easily recognized even by those who are inexperienced in ultrasonic techniques.

The depth of the dissection in relation to the pathologic lesion can be defined by filling the dissected area with saline and placing a surgical sponge within the innermost recesses. These surgical sponges are extremely hyperechoic and serve as excellent markers for the depth of the dissection. By ultrasonography one can determine precisely where to take the biposy specimen or where to resect and can assess thereafter how much residual tumor has been left behind or, on the other hand, whether or not all the tumor has been removed. Ultrasound studies also detect as a bright hyperechoic interface a cannula or needle introduced for location and its relationship to the lesion, as well as the position of ventricular shunts.

The ultrasonic industry is in ferment in developing the ideal intraoperative unit. At present, sector real-time scanning seems to be the most appropriate tool. The unit we are using is a neurosector machine (developed by the ATL Corporation) that has a conical transducer. It is a mechanical sector scanner that produces pie-shaped images instantly in any plane. For use in the operating room, sterile gel is applied to the conical surface of the transducer and thereafter a sterile sheath encases the transducer and the cord. Sterile rubber bands stabilize the sheath. The machine itself has a flat surface; a sterile plastic is placed upon the face of the unit so that the operator can manually touch and manipulate the machine and the tape recorder without breaking sterile technique. The transducer frequency can be changed with a touch of the finger from 3 to 5 or 7.5 MHz. The 3-MHz transducer produces an image across the surface of the brain from one cortical surface to the opposite side. The 5-MHz transducer has a greater resolution but the depth is limited to the midline whereas a transducer of 7.5-MHz frequency produces the highest resolution but has a focal point depth of only 2 cm from the surface. Therefore, this transducer is reserved for superficial lesions. Sterile saline is an effective coupling agent between the transducer and the brain surface.

Because ultrasound does not cause any known biologic harm at the energies used in diagnosis, it is a safe tool to use on the delicate tissue of the brain. Early experience suggests that this technique is appropriate and extremely useful in locating a wide spectrum of intracranial lesions—including neoplasms and infections—and in placing ventricular shunts.

Gretchen A.W. Gooding, M.D.

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BEHIND THE FACE OF HYPERTENSION

New evidence for central control

Whose Tetralogy Is it? A Short History of the Tetralogy of Fallot

MARTIN DUKE, M.D.

Although the clinical and pathologic features of the tetralogy of Fallot have been amply studied, little thought is usually given to the history of this malformation other than for the casual use of the name by which it is known. It may therefore be surprising to learn that a considerable amount of information about this anomaly existed for over 200 years prior to Fallot's well known publication in 1888.[1] The oldest reference can be found in the writings of the 17th century Danish anatomist and theologian Nicolas Steno (Niels Stensen of parotid duct fame) in which he described a fetus with multiple defects[2]—

"The first thing that took our attention and admiration was the unusual form of the great vessels, especially the pulmonary artery which seemed to be something new since it was much more narrow than the aorta .... When I thereafter opened the right ventricle, the (outflow tract) ... was easily connected into the aorta as was also the one from the left ventricle."

An even more detailed description appeared in the *Observationes Anatomico—Pathologicae,*[3] written and illustrated by the great Dutch physician, teacher and linguist Eduard Sandifort in 1777 over 100 years before Fallot's publications. In Book 1, Chapter 1, entitled "De rarissimo cordis vitio" (Concerning a very unusual malady of the heart), a patient is described who had cyanosis after the age of 1 year, extreme fatigue, headaches relieved with venesection, fainting spells, palpitations, and pedal edema, and who succumbed at 12½ years of age. The four salient findings of the future tetralogy of Fallot were fully detailed at postmortem examination—

a) "this artery (pulmonary), having been cut above the valves, showed these to be very small almost rigid ... so that only a very small space was left, which, permitting the entrance of the point of a rather thin stylus, proved (to be) the passageway for this to the right ventricle, and transmitted the same with some difficulty from the ventricle to the artery"

b) "the right (ventricle), if not thicker, had the same thickness as the left"

c) "But how great was the surprise of the onlookers, how great equally was my own surprise, when we saw the point of the finger (inserted in the right ventricle) to stretch into the aorta, which is not at all accustomed to maintain communication with the right ventricle, in conformity with otherwise constant laws of nature!"

d) "The arterial aorta ... showed the same edge, by which the orifice was divided into a larger part, connecting with the right ventricle, and into a smaller part, ascribed to the left ventricle. And thus the arterial aorta was springing from both ventricles, and had to receive all the blood from both."

A historical revisionist might well make an excellent case for naming this complex of congenital abnormalities the tetralogy of Sandifort!

In 1784 William Hunter of Glasgow and London noted a case[4] where "the passage from the right ventricle into the pulmonary artery, which should have admitted a finger, was not so wide as a goose quill; and there was a hole in the partition of the two ventricles, large enough to pass the thumb from one to the other .... The greatest part of the blood in the right ventricle was driven with that of the left ventricle into the aorta, or great artery, and so lost all the advantage which it ought to have had from breathing."

Many other cases were described[5] in these early years including those by Thomas Peacock of London[6] in one of the first comprehensive works on congenital malformations of the heart. Thus, it is clear that the tetralogy was well documented prior to Fallot's article in 1888. Indeed, Etienne-Louis Arthur Fallot himself was well aware of much of this preceeding literature and gave credit to many who had described these lesions before him. Stimulated by having made a clinical diagnosis at the beside that was later confirmed at

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postmortem examination, he summarized the important features of this anomaly, noting in addition that

"cyanosis, especially in the adult, is the result of a small number of well-determined cardiac malformations. One (the tetralogy) is much more frequent than the others since we have found it in about 74 percent of our cases; this is what the clinician should diagnose, and in so doing his chances of error are relatively slight."

In light of the excellent description by many others before him, it seems strange that Fallot was singled out and his name used to identify this malformation. However, one is reminded of the words of Hans Selye[7]—"It is not to see something first, but to establish solid connections between the previously known and the hitherto unknown that constitutes the essence of scientific discovery. It is this process of tying together which can best promote true understanding and real progress." In discussing the difference between *seeing* and *discovering*, Selye adds that Jenner, Harvey, Darwin, and Pasteur were not the first to formulate the ideas and theories that made them famous "but these were the men who really developed these ideas to a point where they became useful." It is perhaps for this reason that the distinction and honor of having his name attached to this anomaly has been rightfully given to Fallot. Others *saw* the tetralogy principally as a pathologic entity—Fallot *discovered* that it could be diagnosed clinically, thus preparing the way for its medical and surgical management in the years ahead.

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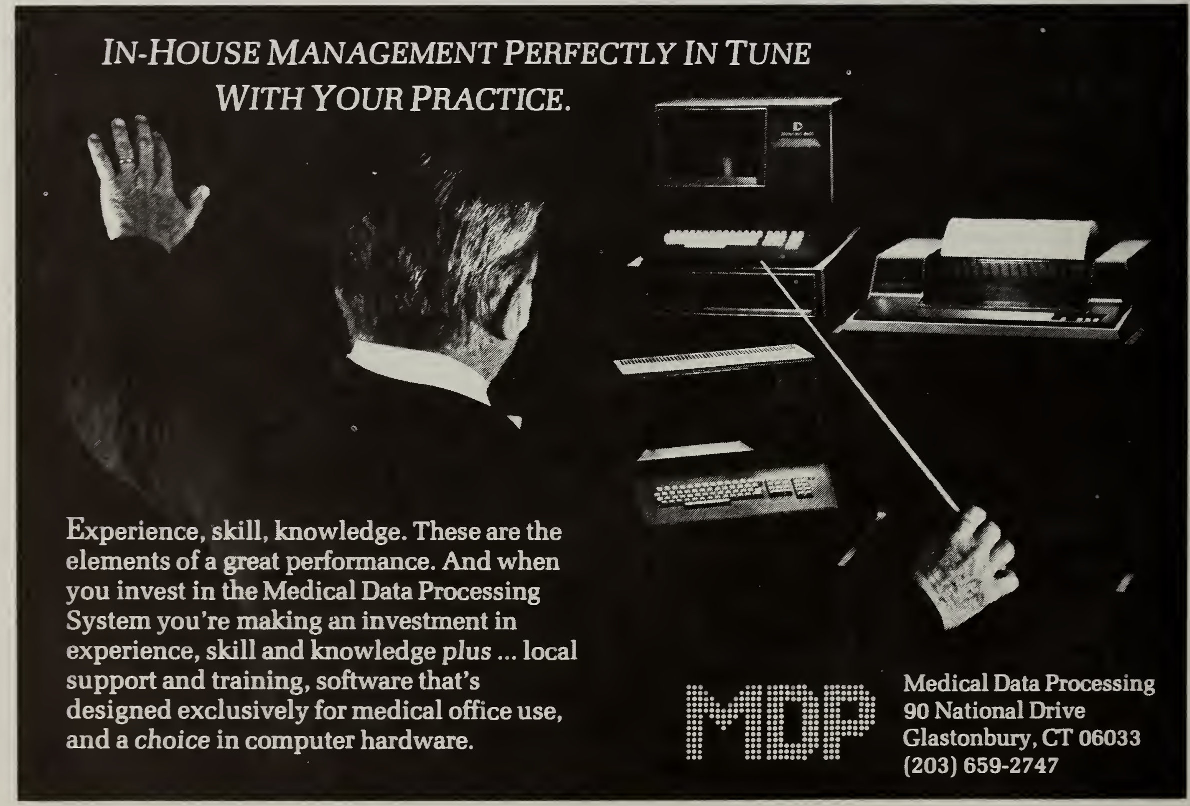

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“Scombroid Poisoning” and Bluefish: The Connecticut Connection

BLAKE DANIELS PRESCOTT, JR., M.D.

ABSTRACT—Scombroid fish poisoning is a toxic form of fish poisoning infrequently recognized and/or reported. It is usually mistaken for an allergic reaction due to its histamine-like response. Three cases resulting from ingestion of bluefish in Connecticut (where it has been a characteristic source of this disease) are described. A review of symptoms and signs in these cases is compared with that reported in the literature from scombroid and non-scrombroid fish pointing out the similarity of syndromes regardless of fish. Culpable fish include many non-scombroid fish involving three taxonomic orders. With no common demoninator from taxonomy, it is suggested that the term “scrombroid fish poisoning” is inappropriate and misleading; “pseudo-allergic fish poisoning” is preferred. Bluefish serve as an example for the pathogenesis, including the enzymatic action of marine bacteria and their production of an elusive “scombrotoxin.” Suggestions are given for the proper handling of bluefish.

Introduction

Of the various food poisonings, there are those that are caused by toxins, and among those toxic food poisonings are those caused by fish containing the toxin within their flesh, i.e., icthyosarcotoxins. Scombroid fish poisoning is such an icthyosarcotoxin, and, indeed, it may well be the most common of this type of problem worldwide.[1,2] This poisoning results in a characteristic syndrome consisting of an apparent histamine type of reaction which mimics, and is usually mistaken for, an allergic reaction. The name “scombroid” indicates the source of this poisoning to be from fish of the suborder Scombroidei and particularly the family Scombridae; however, it has also been well recognized and reported as a result of ingesting a fish of a separate suborder,[6] the dolphin (called mahi-mahi in Hawaii).[3-5] What has not been generally appreciated is the fact that scombroid fish poisoning occurs in another fish taxinomically unrelated to either of the foregoing groups, a fish which is frequently caught by sport fisherman and commercial fisherman alike: Pomatomus saltratix, or, as it is commonly known, the bluefish.[7] The bluefish has a widespread distribution, being caught off the shores of at least five continents;[8] so its association with scombroid fish poisoning has far-reaching implications. And, the bluefish is a prize catch off the shores of the eastern seaboard of the United States in the *warmer months.* This provides ideal circumstances for the action of bacteria indigenous to sea water to start a chain of events which ends in a toxic fish poisoning. *Indeed,* this chain of events may well be initiated long before the fish leaves the boat; a generally unappreciated facet of this problem.

Three cases, all resulting from the ingestion of bluefish consumed in Connecticut are described. A discussion follows the case reports and includes special attention to problems peculiar to the bluefish as well as a general review of the subject. Other non-scombroid fish which have caused this type of poisoning are noted, and the question of the name “scombroid fish poisoning” being a misnomer is raised. A special focus is placed in this paper on problems previously misunderstood and/or considered worthy of further research.

Case Reports

Case #1: On September 14, 1982, a “cardiac” patient was brought in as an “emergency” with apparent tachyarrhythmia. This proved to be a fifty-year-old man with previously documented coronary artery disease presenting with rapid palpitations and a concern about the possibility of something having happened to his heart. In association with this he had noted a peculiar “blotchy” rash. He had a flushed feeling, a mild headache, and some minimal nausea. On examination, he

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had a regular tachycarda of 120, no other clinical change in his previous cardiac status and an erythematous patchy eruption extending in a blotchy pattern from the nipple line up over the neck and head. He was afebrile. Further history indicated that he had just eaten lunch at a nearby restaurant. The lunch consisted of bluefish with potatoes and tea. He had had bluefish in the past without any problem and had no known allergy to any ingestant. It was felt that he possibly had scompbroid fish poisoning, and he was treated with antihistamine; with rapid resolution of all his symptoms.

Case #2: On September 16, 1982, a sixty-two-year-old gentleman presented unexpectedly to the same office, complaining of a "flushed" feeling and a "rapid pulse." He further stated that he was nauseated, had diarrhea, and had discovered, on removing his shirt, that he had a rash. On examination he had a peculiar rash which was erythematous and patchy, dramatically distributed over the upper quarter of his trunk as well as his neck and head, while extending only slightly below the nipple line as a few blotchy patches. His pulse was 128 with a blood pressure of 120/80. On further inquiry, it was discovered that he had just eaten lunch at the same restaurant in Case #1. Indeed, he had not finished eating when he had had the onset of his symptoms. His lunch was a simple one consisting of bluefish, seltzer water, and french fries. He further noted that he had eaten bluefish at the same restaurant one week previously, having only mild nausea for a short time thereafter. He was felt to have scombroid fish poisoning and was treated with epinephrine and antihistamine: with a rapid and complete resolution of his symptoms.

Case #3: Following the second case, steps were taken to notify the restaurant and to take appropriate measures to hold any further serving of bluefish as well as trying to retrieve any remaining bluefish. In addition, the emergency room of the local hospital and the infirmary of the nearby University of Connecticut were contacted in order to alert them to the possibility of cases of scombroid fish poisoning. from the university infirmary, it was discovered later that a student had eaten bluefish at the same restaurant and had the onset of flushing ten minutes thereafter, followed by symptoms of a throbbing head, a general feeling of warmth, and mild chest tightness. She was found to have the characteristic "flushed" rash over her trunk. She responded to antihistamine therapy with a resolution of her symptoms.

Aftermath

The restaurant owner found that he had had only one bluefish, and that had been entirely consumed. Later, a portion of the head was discovered in the garbage and was retrieved for histamine analysis.

No further case of poisoning was brought to light from that restaurant.

On contacting the Connecticut State Health Department, it became apparent that not only did these cases fit the pattern of scombroid fish poisoning as they knew it, but also there were five to six outbreaks per year reported in Connecticut, exclusively from bluefish. It was further noted from their statistics, that these cases were reported in the months of August through October, i.e., the months when bluefish would be "running" off New England shores, and the months of catch which would be warm enough (especially August and early September) to promote bacterial growth in or on fish that are not immediately iced.

On contacting the Center for Disease Control in Atlanta, it was underscored that this problem should in no way be limited to Connecticut, but be reflected in a much broader area.

Discussion

The Clinical Syndrome—Scombroid fish poisoning is one of a number of fish and shellfish poisonings (see Table 1) generally not difficult to differentiate from the other poisonings but very frequently difficult to differentiate from allergic reactions. It is characterized by a

Table 1
TYPES OF FISH AND SHELLFISH POISONING

Name	*Symptoms & Signs*	*Cause*
SCOMBROID FISH POISONING OR *PSEUDO ALLERGIC FISH POISONING*	Flushing of the face, neck, and upper trunk; rapid palpitations; headache; oral burning; and GI symptoms (N, V &/or D).	Histamine-like reaction. Bacterial action on biochemically predisposed fish (no taxonomic common denominator).
CIGUATERA [19]	Acroparesthesiae, GI symptoms, myalgias, weakness and possibly other neurologic symptoms and signs (paralysis—including respiratory-visual changes, reversal of hot and cold, etc.)	Uncertain toxin—possibly a dinoflagellate (Gambierdiscus toxicus) acquired in food chain. Usual fish: grouper, snapper, kingfish, amberjack, dolphin & barracuda.
PUFFER POISONING [20]	Orofacial paresthesiae, other paresthesiae, ataxia, dizziness, shock, desquamation of the skin.	Ingesting skin, gonads, or viscera of puffers, porcupine fishes, sharp nose puffers, and ocean sunfishes.
GYMNOTHORAX POISONING [20]	Severe form of Ciguatera.	Ingestion of toxins in the moray eel.
ELASMOBRANCH POISONING [20]	Mild GI Symptoms and sometimes severe neurologic.	Ingestion of biotoxic liver and flesh from tropical sharks.
PARALYTIC SHELLFISH POISONING [19]	Acroparesthesiae, GI symptoms, "feeling of floating," and possibly more severe neurologic findings (dysphonia, dysphagia, and respiratory paralysis).	Ingestion of bivalve mollusks which acquired neurotoxin of dinoflagellates through food chain.
NEUROTOXIC SHELLFISH POISONING [19]	Paresthesiae, reversal of hot and cold, ataxia and GI symptoms. Aerosolization symptoms of conjuctival irritation, rhinorrhea, and cough.	As above, but with a different, less toxic dinoflagellate. Aerosolizations of dinoflagellate in surf; direct irritatin of human near surf.

histamine-like reaction; and, in the cases presented here, included findings of rapid palpitations, flushing, headache, nausea, diarrhea, tightness in the chest, and a characteristic rash covering the head, neck and uppermost trunk. The rash was a patchy, blotchy, erythematous rash suggesting but not quite meeting the criteria for urticaria. While these symptoms were caused by ingestion of bluefish in this situation, other articles on scombroid fish poisoning have described similar symptoms from fish of the family Scombridae. This family is well described by Collette and Choa[9] and then again by Klawe,[10] and it includes the tunas, bonitos, seerfishes, mackerels, and the butterfly kingfish (see Table 2). A large outbreak resulting from commercially canned tuna occurred in 1973 involving 232 documented people and was reported by Merson et al in JAMA[11] in 1974. That article tabulated the symptoms of 95 interviewed cases and listed nausea, cramps, oral burning or blistering sensation, diarrhea, flushing, headache, rash (including urticaria), vomiting, and palpitations.[11] Symptoms have also been well documented in scombroid fish poisoning from a "non-scombroid (see Table 2) fish which has long been known to cause this snydrome: the dolphin, or, as it is called in Hawaii, mahi-mahi. This is not to be be confused with the completely unrelated porpoise, which is a mammal and sometimes erroneously referred to as a dolphin. A recent article by Garth Dickinson[1] pointed out two cases resulting from a "fishburger" and a fish

Table 2

ABBREVIATED TAXONOMY OF FISHES CAUSING "SCOMBROID" FISH POISONING

(Adapted & Combined from Greenwood,[6] Collette & Chao,[9] & Klawe[10]

DIVISION *SUPERORDER* *ORDER* *SUBORDER* *FAMILY* *SUBFAMILY*	*Examples of Poisoning* *(By Species Where Information Permits)*
I.	
Clupeomorpha	
Clupeiformes	
Clupeoidei	
Clupeidae = *Herrings*	Clupea sprattus[15] Sprat Clupea pilcharous[15] Pilchard
III.	
Paracanthopterygii	
Gadiformes	
Gadoidei	
Gadidae = *Codfish*	Gadus morhua[13] "Rock Cod" = Atlantic Cod
Acanthopterygii	
Perciformes	
Percoidei	
Pomatomidae = *Bluefishes* (only 1 species in this family)	*Pomatomus saltratrix* *Bluefish*
Carangiadae = *Jacks*	(At least 10 different species called jack[7]) "Jack"[13]
Coryphaenidae = *Dolphins*	Coryphaena hippurus Dolphin (= mahi-mahi)[12, 13]
Lutjanidae = *Snappers*	Lutjanus campechanus Red Snapper[13]
Mullidae = *Goatfishes*	(6 species called goatfish are listed[7]) "Goatfish"[13]
Scombroidei	
Scombridae = *Mackerels*[9, 10]	
Scombrinae	
Thunni – Tunas	4 Genera 13 Species 9 called tuna[10] "Tuna"[13, 14] Albacore[13]
Sardini – Bonitos	5 Genera 8 Species 3 called tuna 6 called bonito[10] "Bonito"[13] "Tuna"[13, 14]
Scomberomorini – Seerfishes	18 Species 10 called "Mackerel" Scomberomorus maculatus Spanish Mackerel[13]
Scombrini – Mackerels	2 Genera 6 Species "Mackerel"[10]
Gasterochismatinae	Only 1 species – No example of poisoning found

sandwich made from dolphin. He further pointed out that, while these were served in Bermuda, they had been "imported frozen from the United States," indicating the need for our vigilence no matter how far we are from the original catch. The findings in those two cases from dolphin poisoning included "flushing, a burning sensation in the mouth, lightheadedness, headache, nausea, and palpitations," along with "a diffuse erythema of the face, upper chest and proximal arms."[1] As one can see from the foregoing, the symptoms and physical findings in cases of scombroid fish poisoning are not peculiar to the family Scombridae, and those caused by bluefish are much the same as those caused by dolphin or tuna.

The practicing physician should be alerted to these symptoms and signs, to the fact that they occur so rapidly after the ingestion of the offending fish (from one minute[12] up to three hours,[11] and with the mean time in the case of the 95 tabulated patients afflicted with symptoms from canned tuna of 45 minutes,[11]) and to the rapid resolution of the abnormalities with the administrtion of epinephrine and/or antihistamine. In short, the treatment is symptomatic. Emetics and cathartics may be useful if vomiting and diarrhea have not occurred; however, antihistamines and epinephrine often suffice. If bronchospasm is present, bronchodilators may be used. The practicing physician should also be prepared to inquire about the ingestion of fish that might be incriminated so as to take measures to stop the further consumption of that fish, and to enlist the aid of the public health authorities in accomplishing this.

The Fish—Hughes, et al report scombroid fish poisoning from such scombroid fish as tuna, bonito, albacore, and Spanish mackerel in their tabulation of twenty nine scombroid outbreaks in the United States from 1970 to 1974; however, they also note outbreaks from other non-scombroid fish in addition to dolphin (mahi-mahi) including jack, rock cod, red snapper, and goatfish.[13] Morris, et al tabulated the cases of scombroid fish poisoning of 1975 to 1979 in the United States, and noted that the most common cause of outbreaks was the non-scombroid mahi-mahi during that period. Tuna were implicated in approximately one-third of the outbreaks while *bluefish* accounted for approximately 10% of the outbreaks.[14] In the 1979 summary from CDC, 10 out of 12 outbreaks were reported from "non-scombroid" fish—five of those being from mahi-mahi.[12] So scombroid fish poisoning is frequently from non-scombroid fish.

When considering the taxonomy of the fish causing scombroid fish poisoning, a still more impressive article comes to light. Gilbert, et al report on the features of the first 50 incidents to be reported in Britain from this poisoning. It is first to be noted that these cover the period from 1976 to 1979 with most of the cases being reported in 1979, reflecting a similar lack of recognition of this disease in Britain as in the United States. The fish incriminated were chiefly mackerel. Others included bonito, "sprats," and canned "pilchards."[15] Pilchards and sprats both refer to small, European fish of the "herring" family. These fish are in a different order[6,7] and are of a completely different division[6]—considered to have evolved in a path distinct from others divisions[6] (See Table 2). So, scombroid fish poisoning is not limited to fish of the family Scombridae or even to those of the suborder scombroidei. Furthermore, it is not limited to "perciform" fish. (See Table 2). The common denominator is evidently not a taxonomic one.

It is noteworthy that the common names of fish are generally used in these medical reports. Indeed, sometimes, perhaps out of frustration, the common names used do not even refer to genera but encompass more than one tribe. At other times, only the family name is referred to. Taxonomists point out that this leads to misunderstanding not only within the United States where many of our fish have more than one common name and some different fish have the same common name, but also limits international understanding to an even greater degree. This is eloquently stated in Klawe's article: What is a tuna?[10] Fortunately, since taxonomy does not appear to be a common denominator of this disease, one may avoid becoming embroiled in the ever-changing classification of the fishes.

Perhaps a more appropriate name for "scrombroid fish poisoning" would be *"pseudo-allergic fish poisoning,"* thus alerting clinicians to the clinical syndrome rather than misleading them into thinking that a particular family of fishes is responsible for the poisoning.

The Bluefish—The bluefish poses special problems of its own. Ranging from Argentina to Nova Scotia off South and North America, it is found as well in the Atlantic off Africa and Europe. Furthermore, it is found in the Mediterranean and Black Seas as well as the eastern Indian Ocean.[7] It is after they spawn that they become ferociously hungry and succumb to fishermen off New England coasts; this correlates then with the warmer months, with fishing for bluefish (or "blues") often being heavy in August and September. This coincidence of warm weather and heavier catches of bluefish may explain why the bacterial activity would be greater, acting on the flesh of the bluefish to release histamine from the inherent precursor histidine. For it is at least thought that the common biochemical denominator of these "oily fish" is their free L-histidine content. A variety of bacteria have been implicated in causing this reaction. These marine bacteria are present in the sea water and present on the skin of the fish; so that a gaffed fish, or a fish excessively handled and washed in sea water (whether as part of the cleaning process or not) may be one at special risk for either the proliferation of the bacteria and/or the encouragement of their enzymatic action. Supposedly, this bacterial action results in the liberation of "scombrotoxin," an uncertain chemical evidently heat stable (i.e., not eliminated by canning or cooking as was thought by some[16] and possibly including histamine and "saurine." Saurine is named after Saury which is a dried fish delicacy in Japan, and it was in Japan that studies were done to try to isolate these components of scombrotoxin.[17,18] It is felt that the enzymatic action of the bacteria, the most noteworthy being *Proteus morganii* and Klebsiella species, cause the decarboxalation of histidine to histamine; and it is noted that this occurs optimally at between 20° and 30° Celsius, tempertures frequently met in August and September while fishing for bluefish.

The foregoing suggests that in order to avoid a bluefish becoming toxic, one should not gaff the fish or handle the fish excessively, and particularly not to wash it further in sea water while handling or cleaning the fish, but to put the fish in ice immediately and keep it iced thereafter.

The explanation of pathogenesis of this fish poisoning leaves a number of unanswered questions. How can histamine be the culprit, when it is not thought to be active when taken by mouth and large doses of oral histamine generally do not cause illness? In addition, our intestine normally contains histamine produced by the activity of bacteria. Accordingly, explanations have been set forth to implicate saurine or other heat stabile substances as the toxin. Still another possibility is that some other substance is produced which permits the absorption of histamine.

Unfortunately, with bluefish, as with other fish causing scombroid fish poisoning, one cannot depend upon the smell or taste of the suspect fish as indicating possible poisoning. While such fish may taste "peppery," or may even look or smell "spoiled," they may appear perfectly normal with no abnormal smell or taste. In the case of the major outbreak from canned tunafish, "honeycombing" was noted and felt to be a sign of decomposition; however, this too is not necessarily present.[11]

Similarly, analysis of the incriminated fish for histamine level is not always dependable. It has been shown that a piece of fish causing scombroid poisoning may have a high histamine level (50 or more milligrams of histamine per 100 grams of fish muscle), while a piece not more than a centimeter away may well have a normal or low level (less than 20 milligrams per 100 grams). The small piece of head retrieved in the case of the bluefish poisoning reported in this paper had a level of less than 10 milligrams per 100 grams.[8] Thus, we have no specific test at this time to diagnose scombroid fish poisoning.

Conclusion

The bluefish has served as an example of a *pseudo-allergic fish poisoning syndrome:* A syndrome which should not reoccur when challenged with non-toxic bluefish on subsequent occasions. As a non-scombroid fish, the bluefish alerts us to the tendency to be misled by the name "scombroid fish poisoning." In considering the handling of bluefish, we see that the process of toxin production may be initiated long before the boat reaches shore. Thus, an educational program directed toward our sports fishermen should be appropriate. It would also be important to have a regulatory program for commercial fishermen so that sampling of fish could be carried out in conjunction with continued research as to the exact pathogenesis of this disease.

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Legal Issues in Malpractice Claims

Malpractice claims usually involve multiple allegations. Most, of course, are medical related, while others are legal in nature. For example, lack of informed consent is one of the principal types of legal issues involved. From 1979 to 1982, physicians insured by St. Paul Fire and Marine reported 185 claims in which "lack of informed consent" was the *primary* allegation.

Between May 1982 and September 1983, St. Paul-insured hospitals reported an additional 42 claims in which their hospital was named in an informed consent claim. While these are not large numbers in and of themselves, it is important to recognize that informed consent issues are a significant problem. Because The St. Paul's claims analysis system identifies only the primary allegation for each claim, it is impossible to monitor the actual number of claims in which lack of informed consent or other legal issues are a *contributing factor.* ■

PHYSICIAN MALPRACTICE ALLEGATIONS
—LEGAL AND MISCELLANEOUS ISSUES
Reported 1979 to 1982

PRIMARY ALLEGATION	NUMBER OF CLAIMS	AVERAGE COST
LACK OF INFORMED CONSENT	185	$ 17,713
EMOTIONAL TRAUMA	134	9,964
ABANDONMENT	89	15,890
BILLING PROBLEMS	85	2,321
FAILURE TO REFER	45	23,766
FAILURE TO DISCLOSE, INFORM PATIENT OF CONDITION	43	10,859

HOSPITAL MALPRACTICE ALLEGATIONS
—LEGAL ISSUES
Reported May 1982 to September 1983

PRIMARY ALLEGATION	NUMBER OF CLAIMS	AVERAGE COST
LIABILITY FOR ACTS OF OTHERS	53	$ 20,043
LACK OF INFORMED CONSENT	42	12,171
FAILURE TO ADMIT	38	13,188
MEDICAL STAFF PRIVILEGES	27	32,567
PATIENT LEFT HOSPITAL (AGAINST MEDICAL ADVICE)	18	13,692
OTHER LEGAL ISSUES	64	11,589

—*Malpractice Digest,* December 1983

The Case for Incorporating After TEFRA

(Second of Two Parts)

MARK E. KROPIEWNICKI, J.D., LL.M., GEOFFREY T. ANDERS, J.D., CPA, CPBC
AND LEIF C. BECK, LL.B., CPBC

Last month, in the first article in this series of two, we noted that the Tax Equity and Fiscal Responsibility Act of 1982 ("TEFRA") made a number of changes that have caused doctors and their advisors to question the continued viability and advisability of the professional corporation. We suggested that each doctor's situation would need to be closely analyzed to determine whether to incorporate a practice or whether to liquidate an existing professional corporation.

Towards that end, in Part I, we considered the various tax and non-tax advantages of the professional corporation. Now in Part II, we will discuss the disadvantages and extra costs relating to a professional corporation as well as some circumstances where it is advisable to liquidate an existing professional corporation and some situations where it is preferable to incorporate. Finally, we have included a worksheet to help analyze your situation in deciding what to do.

Corporate Disadvantages

Startup Costs. Fees for an attorney, accountant and perhaps an actuary will comprise the bulk of the costs necessary to incorporate a practice and to arrange its various benefit programs and affairs. If properly planned the costs for notices, various filing fees, stationery, signs, etc. occasioned by incorporation are usually insignificant. Actual cost will depend upon the number of physicians and the amount of involvement required of the advisors to analyze, decide upon and implement the doctors' plans for the corporation. Total startup costs, including setting up the corporation, establishing fringe benefit plans, preparing employment agreements, shareholders' agreements and other related documents but excluding retirement plans, could total $2,000 or more over the corporation's first year. Solo physician incorporation, except in unusual cases, should cost substantially less. Actually, the act of incorporating a practice involves little cost—but the corporate entity alone does little good.

Employee Taxes. Payroll tax costs for corporate physician-employees will add up to at least a few hundred dollars year after year. The incorporated doctor will pay unemployment tax and workmen's compensation insurance premiums on his salary. These various taxes paid by the corporation are, of course, deductible by it and consequently lower their effective cost.

An incorporated doctor presently pays more for Social Security taxes than does an unincorporated doctor; however, starting in 1984, the Social Security cost for unincorporated physicians will begin to rise and will actually exceed the effective costs for incorporated doctors. After 1989, it is anticipated that the effective rates for both will be identical.

Other State Taxes. Most states and some local governments impose corporate income, franchise, capital stock or other corporate taxes which add usually minimal amounts to the ongoing yearly costs of a professional corporation. Solo doctors and unincorporated groups are not subject to those types of taxes.

Ongoing Expenses. Since federal, state, and perhaps local corporate income tax returns, perhaps other federal and state tax returns and other forms, and additional ongoing legal services are required, the incorporated solo doctor clearly has additional legal and accounting expenses that the unincorporated solo doctor does not incur. The incorporated group usually will not have much additional legal and accounting fees as an ongoing matter since group arrangements generally require continuing attention by advisors whether incorporated or not.

Cost Of Liquidating A Corporation. Upon liquidating a corporation, a one time cost of perhaps $1,000 to $2,000 for legal and accounting fees will be incurred. Expert tax advice is often needed to prevent unnecessary tax costs and complications. For example, in anticipation that professionals might want to liquidate, TEFRA provides special rules, applicable only in 1983 and 1984, for liquidating professional corporations. Those rules reduce some of the usual negative tax consequences of a corporate

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liquidation by providing that the corporation's accounts receivable will not be automatically recognized as income nor will the practice's goodwill be taxed to the unincorporated doctors who continue the practice.

However, this special rule does not totally eliminate the tax due upon liquidation and tax may also be due because of recapture of investment tax credit and depreciation. Thus, it is clearly necessary for the practice's tax advisors to determine whether it is best to use this special liquidation rule or perhaps some other tax rule governing corporate liquidations. The practice advisors should be involved in the decision to properly plan ahead for whatever is eventually decided.

After liquidating a corporation involving a group practice, a partnership agreement will be needed to translate the terms and agreements of the previous corporate arrangements into an agreement legally binding the doctors in their unincorporated status. Consequently, there will be additional costs for preparing a partnership agreement and any other related agreements.

Equipment Purchases. Often it has been desirable for the doctor or doctors to purchase equipment for the practice, either individually or in a partnership, and to lease it to their corporation. The advantage of this approach is to secure the tax benefits (primarily investment tax credit and depreciation) for the doctors' individual tax returns. A professional corporation typically has little or no use for the investment tax credit since most practices purposely have little or no taxable income. The Internal Revenue Service has made it increasingly difficult to meet the tax law requirements to nail down the investment tax credit personally in a corporate lease situation. Unincorporated physicians can definitely take the investment tax credit personally without difficulties. Thus liquidating a corporation or foregoing incorporation may be beneficial to capital intensive practices.

Miscellaneous. The Internal Revenue Service may make an unreasonable compensation claim against the incorporated doctor with very high income. If successful, the corporation's physician-employee is still taxed on all of the income received from the corporation but the corporation is denied a tax deduction for the unreasonable portion of the doctor's salary which is treated as a nondeductible dividend. The corporation then pays corporate income taxes on the dividend portion and, as a result, that portion of the income is taxed twice—once to the corporation and again to the doctor. The unreasonable compensation concern is not present where practice revenues result from the doctor's personal efforts. However, where substantial revenues are generated by other personnel under the doctor's supervision, unreasonable compensation is a potential problem.

Unincorporated doctors have no reasonable compensation problems since they are automatically taxed on all of the practice's earned income. Similarly, the unincorporated doctor avoids various other corporation tax problems and concerns such as accumulated earnings tax and disregard of the corporate entity by the Internal Revenue Service.

There are also no serious year-end bonus, constructive dividend, etc. problems if not incorporated. Similarly, there is no tax need for regular annual or semi-annual meetings with corporate advisors although such meetings and regular input from advisors is often desirable in any practice format.

Comparison of Advantages and Disadvantages

Having described the numerous advantages and disadvantages of the professional corporation, we have prepared and included below, a worksheet to compare the extra costs of corporate status against the benefits to be derived. The worksheet can be used in deciding whether to incorporate an existing medical practice or in determining whether to liquidate an already existing professional corporation. It should be kept in mind that the worksheet is only useful in comparing those items which can be quantified.

Worksheet

Corporation Fringe Benefits

*Net cost (i.e. cost for doctors less cost for staff as required by law or decided upon by the doctors of:

Health insurance premium		$
$50,000 group-term life insurance premium*		
Disability insurance premium		
MERP*		
DEP		
Employee award program ($400/year/doctor)		
Cafeteria Plan*		
VEBA*		
EBT*		
Other fringe benefits*		________
		$

Less:

Corporation Ongoing Costs

Extra yearly costs over that for an unincorporated practice:

Additional legal fees	$	
Additional accounting fees		
Retirement plan administration (same if self-trusted Keogh plan)		
Extra payroll taxes on doctors' salaries		
Other state corporate taxes		
Other miscellaneous costs	________	(________)
Difference		$ ________

When to Incorporate

1. Incorporation makes sense when the ongoing benefits afforded by the professional corporation sufficiently exceed the ongoing extra costs (as measured in worksheet number 1 above) to recoup the initial startup costs of the corporation within perhaps two or three years. For example, if a doctor has high uninsured medical or dental expenses such as for orthodontic work, the benefit of a Medical Expense Reimbursement Plan, a Diagnostic Medical Expense Reimbursement Plan or a Cafeteria Plan to cover such expenses might easily exceed the initial and ongoing costs of incor-

porating the practice. Based on this type of analysis, it would be favorable to incorporate only in unusual circumstances where the corporate fringe benefits would be used significantly by the doctors and staff costs for those benefits are relatively minimal.

2. Incorporate when the still favorable aspects of qualified corporate retirement plans such as the ability to borrow and possible tax-free payout in case of disability are significantly desirable. The other corporate fringe benefits availed of should offset most, if not all, of the extra and initial costs of incorporating.

3. Incorporate when payments for goodwill or other non-deductible items are significant, such as where another practice is purchased, and can be paid more cheaply with the corporation's before-tax dollars.

4. A group medical practice should consider incorporation to limit individual doctor's liability for malpractice of a partner. Incorporation is usually less expensive than yearly cross-partner liability insurance.

5. A solo doctor might consider incorporating within five to ten years of retirement in order to use the corporation as an "extra retirement plan" by accumulating dollars in the corporation. Those accumulations can be later liquidated out under favorable (capital gain) tax circumstances.

6. Incorporation may also be warranted where any of the other corporate advantages previously mentioned in Part 1, such as the better management format, interest-free loans to shareholders, or the shifting of income between personal tax years and the like are considered highly beneficial. By themselves, it is likely that those benefits probably would not favor incorporation unless combined with a number of the otherwise available fringe benefits.

When to Liquidate

1. If the worksheet shows that the extra costs of maintaining the professional corporation exceed the benefits derived from it, liquidation might be advisable. This could happen where the doctors are not taking full advantage of the fringe-benefits available to them or where costs for staff benefits are excessive. That, however, is not all that needs to be considered since, as stated before, there are not insignificant tax and legal costs which will be incurred to liquidate the corporation and to set up the arrangements, if necessary, for an unincorporated group. The legal and accounting fees and the income tax due by reason of the liquidation and the investment tax credit and depreciation recapture could be so high as to completely outweigh the excess of extra corporate costs over benefits.

If the benefits of the corporation equal or exceed costs, it is best not to liquidate since the extra costs of and the income tax caused by having the corporation liquidated, would surely swing the balance towards remaining incorporated.

If the cost-benefit analysis indicates liquidation, some of the intangible or immeasurable benefits may nevertheless favor maintaining the corporation. It might also be desirable to maintain the corporation since there would be no disruption of the way the doctors deal with the corporation and each other.

2. Doctors with very high incomes generated in great part by the efforts of others than the physicians, run the risk of unreasonable compensation claims by the Internal Revenue Service as previously discussed. For example, rehabilitation and physical therapy centers where the doctor performs no significant personal services but which generate substantial income which is paid out of the professional corporation as salary to the doctor, fit into this category. It would likely be best to liquidate the corporation under such circumstances despite the distinct benefit of the various fringe benefits available to the doctor in the professional corporation.

3. TEFRA also created tax difficulties for partnerships of professional corporations (doctors who incorporated as a member of a partnership) and for incorporated doctors or groups providing substantially all services for one other entity (for example, providing all services to a hospital on a contracted payment or payment schedule basis). The difficulty in this situation arises from the ability of the Internal Revenue Service to reallocate income, deductions, etc. between the individual doctor and the corporation to whatever degree is considered necessary to accurately reflect income and to prevent avoidance or evasion of federal income tax. This rather wide ranging authority for the Internal Revenue Service can be disastrous to some doctors. Recently proposed regulations provide a "safe harbor‘ provision, that is probably unworkable in most instances since the limits of that provision, in any given year, could be easily exceeded. Consequently, it is clear that liquidation in the above situations should be considered as an alternative.

4. An incorporated solo practitioner who is not interested in using the corporation as an extra retirement plan, as discussed above, might be advised to liquidate as a preface to eventual retirement while taking advantage of the special liquidation tax rule available in 1983 and 1984. When the doctor eventually retires, the lack of the corporate entity tends to make things "cleaner" when wrapping up the doctor's practice affairs.

Conclusion

When dealing with already existing professional corporations, unless the specific reasons above mandate liquidation, most will be better off to continue incorporated as long as the extra costs of the professional corporation are about equal to the fringe benefit advantages for the doctor or doctors. The costs of liquidation would weigh heavily against liquidating in this case.

Most existing professional corporations, therefore, probably should remain in existence. The structure of the corporation and the management format afforded by it are comfortable to many doctors and it provides a good basis for the doctors to run and maintain the practice. As long as that is the case, it makes sense to keep the corporation as is.

Most existing professional corporations, therefore, probably should remain in existence. The structure of the corporation and the management format afforded by it are comfortable to many doctors and it provides a good basis for the doctors to run and maintain the practice. As long as that is the case, it makes sense to keep the corporation as is.

It is also possible, although not presently expected, that Congress may reverse itself and again make the professional corporation the favored vehicle for professionals. Additionally, over the years, Congress may provide additional fringe benefits which may only be available to physician-employees in a professional corporation and not to unincorporated doctors.

It will be the unusual practice that will incorporate in the future, barring unforeseen changes in tax or other laws. The limited liability available through the professional corporation will be appealing to many doctors in group situations. Some of the other reasons previously discussed could also influence the decision to incorporate. However, if your practice is not presently incorporated, be sure not to incorporate only for the sake of incorporating. Unless there are specific reasons for doing so, there will be little advantage in incorporating and probably extra costs which can be avoided as unnecessary.

It should be clear from all that has been said in these two articles that expert advice is needed in order to make a proper decision. Your advisors should be involved early on in any decision to be made along these lines. The decision to incorporate or liquidate is ultimately in the hands of the doctor, however, it is unlikely that an informed and well reasoned decision will be reached without proper input and advice.

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Physician Responses to Competition

AMA CENTER FOR HEALTH POLICY RESEARCH

Competition facing physicians is increasing rapidly. Several factors have contributed to this trend. Rising health care costs have resulted in greater cost-consciousness among purchasers of health care services. The number of physicians has increased at a rate four times faster than the population since 1970. At the same time, the costs of practicing medicine have been rising sharply. These pressures are making it more difficult for some physicians to attract and retain patients and are heightening physician concern over the cost-effectiveness of their practices.

This report focuses on physician responses in adjusting to a more competitive environment. The types of responses examined include:

- changes in characteristics of practice services, and
- adoption of new marketing strategies and techniques.

The report is based on information from the 4th quarter 1982 survey of the Socioeconomic Monitoring System (SMS). The survey included interviews with 1,215 physicians from a sample representative of the population of all non-federal patient care physicians excluding residents. The survey response rate was 63%.

Changes in Characteristics of Practice Services

Three aspects of practice services in which changes might be expected, in response to competition, are: the number of housecalls made, the number of scheduled week-end and evening office hours, and the number of non-physician personnel employed by physicians. An increased number of housecalls and scheduled week-end and evening office hours are approaches to increasing the accessibility of a physician's services and alleviating problems in attracting patients. Increased employment of non-physician personnel may reflect two different types of responses to competition. First, it may indicate an effort to improve practice productivity and reduce the cost of services delivered. It may also reflect an expansion of the range of services provided by physicians in their offices in an effort to attract larger patient bases.

The changes that have occurred in these three aspects of practice services in the last two years are shown in Table 1. Only 8% of physicians are making more housecalls and only 5% are scheduling more hours on week-ends and in the evening. Slightly greater percentages of all physicians are actually providing fewer of each of these services than two years ago. Two factors may account for the apparent lack of response to competitive pressure in these dimensions of practice services. First, there may not be an effective patient demand for these services. Hospital emergency services may be viewed as satisfactory substitutes in most instances for physician housecalls or office hours outside the normal work week. Second, physicians may not regard the benefits of these services as warranting the cost of their time when compared with other methods for responding to competitive pressures.

A more evident impact of competition is suggested by the increased employment of non-physician personnel by 22% of physicians in the last two years. At the same

Table 1
CHANGES IN CHARACTERISTICS OF PRACTICE SERVICE IN THE LAST TWO YEARS

	*Percent of Physicians by Years of Practice**		
Current Number Compared to 2 years Ago	*All Physicians*	*10 Years or less*	*Over 10 Years*
Housecalls per month			
More	8	11	7
Same	77	80	75
Fewer	14	9	17
Hours scheduled for evening			
More	5	12	2
Same	85	76	88
Fewer	10	12	9
FTE non-physician employees under physician's supervision			
More	22	34	18
Same	67	59	71
Fewer	11	8	12

*Percents may not add to 100 due to rounding. Percents are accurate within ± 3%.

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The AMA Center for Health Policy Research directs the Socioeconomic Monitoring System in cooperation with the AMA Division of Survey and Data Resources..

time, only 11% of physicians have reduced the size of their non-physician staff.

Since physicians with more years of practice generally have better developed practices, they may be expected to experience less of an impact from competitive pressures than younger physicians. This expectation is confirmed by the larger percentage of physicians with 10 or fewer years of practice that are making changes in characteristics of their services compared with those with more practice years. The response by younger physicians is particularly strong in the hiring of non-physician employees. While 34% of young physicians are making greater use of non-physician staff than two years ago, only 18% of more experienced physicians have responded to competition in this manner.

Adoption of Marketing Strategies and Techniques

Although less commonly employed in the medical sector than in other sectors of the economy in the past, marketing strategies and techniques may be more frequently used by physicians to identify patient needs and attract patients as the competitive pressures increase. The SMS survey asked physicians about eight particular marketing strategies or techniques they may have used in the last five years to learn about the extent to which this type of response to competition is already occurring. The different marketing strategies and techniques asked about are listed in Table 2.

Altogether, 40% of physicians have employed at least one of the marketing approaches. The most common measure has been studies of community demographics to assess patient needs. Of physicians reporting, 27% have made such studies in the last five years. In addition, 13% of physicians have used surveys to learn about patient satisfaction with various aspects of their practices, 11% have opened satellite clinics and 9% have advertised their practice in the media. Smaller percentages of physicians have adopted the other four approaches—initiating a patient newsletter, hiring a marketing consultant, developing marketing plan for their practice and locating their practice in a non-traditional setting, such as a storefront or shopping center.

As shown in Table 3, the extent to which physicians have adopted marketing approaches varies by physician characteristic. Similar to their stronger response in changing their services, physicians in practice 10 years or less are more likely than older physicians to have adopted new marketing approaches in the last five years in response to competition.

While only 32% of physicians in solo practice have employed some marketing strategy, 53% of those in group and other types of practice have employed some marketing in the last five years. This suggests that many of the marketing approaches considered may be more cost-effective in non-solo practices because of the ability to spread costs over larger numbers of physicians.

Differences in the extent of marketing responses to competition were also found by region and specialty group. In the West, 48% of physicians adopted marketing responses in contrast to 40% of physicians in all regions combined. This is probably explained by greater competitive pressures in the West due to a higher physician-population ratio than in the rest of the country. By specialty, 51% of medical specialists have used marketing strategies and techniques in the last 5 years compared to only 38% of surgical and other specialists and 33% of general and family practitioners. The reason for these differences by specialty is not directly apparent.

Table 2

MARKETING STRATEGIES AND TECHNIQUES EMPLOYED BY PHYSICIANS IN THE LAST FIVE YEARS

Strategy or Technique Employed in Last 5 Years	*Percent of Physicians*
ANY MARKETING STRATEGY OR TECHNIQUE	40%
Studied demographic information on your community for its effects on your practice in coming years	27
Used surveys to learn about patient satisfaction with various aspects of your practice	13
Opened a satellite office or ambulatory care center	11
Advertised your practice on radio or TV or in a newspaper or magazine	9
Developed a patient newsletter	8
Employed an advertising, public relations or marketing firm or consultant	4
Developed a written marketing plan for your practice	4
Located practice in a "non-traditional" setting, such as a shopping center or store front	1

*Percents are accurate within ± 2%.

Table 3

USE OF MARKETING STRATEGIES AND TECHNIQUES IN THE LAST 5 YEARS BY PHYSICIAN CHARACTERISTIC

Physician Characteristic	*Percent of Physicians Employing any Marketing Strategies or Techniques**
Years of Practice	
10 or less	46
More than 10	38
Type of Practice	
Solo	32
Group and other	53
Region	
Northeast	39
North Central	41
South	35
West	48
Major Specialty Group	
General and Family Practice	33
Medical	51
Surgical	38
Other	38

*The strategies and techniques considered are the same as those in Table 2. Percents are accurate within ± 3%.

Cancer Chemotherapy

THE MEDICAL LETTER

Chemotherapy can now produce long-term disease-free remissions in patients with some types of cancer. Drugs can cure patients with choriocarcinoma, Hodgkin's disease, acute lymphocytic and myelogenous leukemia, testicular cancer, and diffuse histiocytic lymphoma (VT DeVita Jr, et al, Ann Intern Med, 92:587, 1980; SL George et al, N Engl J Med, 300:269, 1979; E Frei III, Science, 217:600, 1982). In some types of cancer, adjuvant chemotherapy in combination with surgery or radiotherapy, or both, has improved survival rates for patients with a high risk of disseminated micrometastases (M Perloff et al in JF Holland and E Frei, eds, *Cancer Medicine,* 2nd ed, Philadelphia:Lea & Febiger, 1982, p 515). Most chemotherapeutic regimens that can achieve cure or major prolongation of survival use combinations of drugs.

DIFFERENT TYPES OF TREATMENT—Surcal excision, the preferred method of treatment for most primary circumscribed tumors, can cure a high percentage of patients with many different types of cancer. **Radiation therapy** is the primary treatment for some types of malignancy, including some patients with Hodgkin's disease, non-Hodgkin's lymphoma, some stages of cervical cancer, and many malignant tumors of the head and neck. Radiation is also used in conjunction with surgery for other tumors, including endometrial cancer and soft tissue sarcomas, and can also be useful for local control or palliation of many other types of malignancies. Radiation therapy is frequently used in combination with chemotherapy, but the toxicity of both may be increased when they are used at the same time or sequentially. **Hormonal treatment,** in the form of ablation or pharmacological doses of hormones or antihormones, is beneficial in some types of cancer; in breast cancer, inability to demonstrate estrogen receptors can identify tumors not likely to respond to hormonal treatment.

TOXICITY—Some anticancer drugs may damage the nervous system, heart, lungs, kidneys, or other organs. Adverse effects of chemotherapy frequently include nausea and vomiting and bone marrow depression. Some of these drugs themselves are carcinogenic. Many of the drugs used in cancer chemotherapy can be harmful to the fetus if taken during pregnancy; women and men should be warned to avoid conception while they are being treated with these agents.

THE TABLES—The tables that follow list the drugs currently used for treatment of major types of cancer. They are not meant as a guide to selection of drugs for individual patients and do not describe doses, sequences, modes, or timing of administration. Some drugs are used for indications for which they have not been approved by the US Food and Drug Administration. Commercially available anticancer drugs and their adverse effects are listed in Table II. Table III lists some drugs usually available only from the National Cancer Institute.

TABLE I – DRUGS COMMONLY USED FOR DIFFERENT TYPES OF CANCER

Cancer Type	*Drugs Currently Preferred*	*Alternative Drugs or Others with Reported Activity*
	DISEASES IN WHICH CHEMOTHERAPY HAS MAJOR ACTIVITY	
Acute lymphocytic leukemia (ALL)	Induction: vincristine + prednisone ± asparaginase or doxorubicin Prophylaxis of CNS disease with intrathecal methotrexate ± radiotherapy Maintenance: combination chemotherapy with methotrexate + mercaptopurine or other combinations	Daunorubicin, cyclophosphamide, cytarabine, thioguanine, vindesine*, teniposide*, mitoxantrone*, etoposide*

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Cancer Type	*Drugs Currently Preferred*	*Alternative Drugs or Others with Reported Activity*
Acute myelocytic leukemia (AML)	Daunorubicin + cytarabine ± thioguanine	Amsacrine*, azacitidine*, teniposide*, etoposide*
Hodgkin's disease	Mechlorethamine + vincristine + procarbazine + prednisone (MOPP) Doxorubicin + bleomycin + vinblastine + dacarbazine (ABVD) + cyclophosphamide MOPP alternated with ABVD	Lomustine, carmustine, hexamethylmelamine*, etoposide*, teniposide*, streptozocin
Non-Hodgkin's lymphoma, Diffuse histiocytic lymphoma	doxorubicin + cyclophosphamide + vincristine + prednisone (CHOP) ± bleomycin ± procarbazine Cyclophosphamide + vincristine + procarbazine + prednisone (COPP) Cyclophosphamide + vincristine + methotrexate + prednisone	Bleomycin, chlorambucil, lomustine, carmustine, cytarabine, hexamethylmelamine*, etoposide*, teniposide*, amsacrine*, asparaginase, methotrexate
Burkitt's lymphoma	Cyclophosphamide Cyclophosphamide+vincristine+methotrexate	Carmustine, methotrexate, ifosfamide*
Wilms' tumor**	Dactinomycin + vincristine	Doxorubicin, cyclophosphamide
Ewing's sarcoma**	Cyclophosphamide + doxorubicin + vincristine	Dactinomycin
Embryonal rhabdomyosarcoma**	Vincristine + dactinomycin + cyclophosphamide (VAC) ± doxorubicin	Methotrexate, thiotepa
Osteogenic sarcoma**	Doxorubicin and/or high-dose methotrexate+ leucovorin rescue ± bleomycin ± cyclophosphamide ± dactinomycin	Melphalan, mitomycin, cisplatin
Breast cancer**	Hormones: estrogens and tamoxifen Chemotherapy: cyclophosphamide + methotrexate + fluorouracil ± prednisone Cyclophosphamide + doxorubicin ± fluorouracil	Vincristine, vinblastine, mitomycin, mitolactol*, mitoxantrone*, teniposide*, androgens, progestins, prednisone, aminoglutethimide
Choriocarcinoma	Methotrexate ± dactinomycin	Vinblastine, chlorambucil, bleomycin, etoposide*, cisplatin
Testicular	Vinblastine + bleomycin + cisplatin	Vinblastine + dactinomycin + bleomycin + cyclophosphamide + cisplatin (VAB-6) Doxorubicin, etoposide*, cyclophosphamide, methotrexate, mithramycin, dactinomycin, melphalan, chlorambucil

DISEASES IN WHICH CHEMOTHERAPY HAS MODERATE ACTIVITY

Chronic myelocytic leukemia (CML) Stable phase	Busulfan	Mitobronitol*, hydroxyurea, mercaptopurine, thioguanine, melphalan
Acute phase	Daunorubicin + cytarabine + vincristine + prednisone ± thioguanine	Amsacrine*, azacitidine*, vindesine*
Chronic lymphocytic leukemia	Chlorambucil ± prednisone	Cyclophosphamide, vincristine
Non-Hodgkin's lymphoma Follicular lymphoma	Cyclophosphamide or chlorambucil or vincristine or prednisone or etoposide* (combinations not demonstrably superior to single agents)	Cytarabine, asparaginase, methotrexate
Myeloma	Melphalan (or cyclophosphamide)+ prednisone	Carmustine, vincristine, lomustine, doxorubicin

Cancer Type	*Drugs Currently Preferred*	*Alternative Drugs or Others with Reported Activity*
Mycosis fungoides	Combination chemotherapy as in Hodgkin's disease or non-Hodgkin's lymphoma	Mechlorethamine (topical), vinblastine, methotrexate
Retinoblastoma	Doxorubicin + cyclophosphamide	
Neuroblastoma	Doxorubicin + cyclophosphamide Cyclophosphamide or vincristine or doxorubicin	Mechlorethamine, daunorubicin, decarbazine, vinblastine, prednisone, cisplatin, teniposide*
Adrenocortical carcinoma	Mitotane	Doxorubicin, aminoglutethimide*
Bladder	Cisplatin and/or doxorubicin Thiotepa instillation	Mitomycin, cyclophosphamide, fluorouracil, methotrexate, mitomycin instillation
Brain	Carmustine or lomustine	Semustine*, procarbazine, doxorubicin, vincristine
medulloblastoma	Vincristine + carmustine ± mechlorethamine ± methotrexate Mechlorethamine + vincristine + procarbazine + prednisone (MOPP)	
Lung small cell (oat cell)	Doxorubicin + cyclophosphamide + vincristine	Cyclophosphamide+lomustine+methotrexate Procarbazine, hexamethylmelamine*, etoposide*, mechlorethamine
Cervix	Cisplatin ± methotrexate ± bleomycin	Cyclophosphamide, vincristine, mitomycin
Endometrial	Megestrol acetate or hydroxyprogesterone caproate or medroxyprogesterone Doxorubicin and/or cyclophosphamide	Fluorouracil, tamoxifen
Gastric	Fluorouracil + doxorubicin + mitomycin Fluorourocil + doxorubicin + semustine*	
Head and neck, squamous cell	Bleomycin + cisplatin ± methotrexate	Vinblastine, cyclophosphamide, fluorouracil, mitomycin, doxorubicin
Islet cell carcinoma	Streptozocin ± fluorouracil	Cyclophosphamide, doxorubicin, dacarbazine
Ovary	Melphalan (or cyclophosphamide) ± cisplatin ± doxorubicin	Hexamethylmelamine*, fluorouracil, chlorambucil, thiotepa, megestrol acetate
Sarcomas (soft tissue)	Doxorubicin (± dacarbazine + vincristine + cyclophosphamide)	Methotrexate
DISEASES IN WHICH CHEMOTHERAPY HAS MINOR ACTIVITY		
Pancreatic***	Fluorouracil + doxorubicin + mitomycin	Mitomycin, doxorubicin, streptozocin, semustine*
Liver***	Doxorubicin	Fluorouracil, floxuridine
Colorectal	Fluorouracil	Semustine*, lomustine, mitomycin, streptozocin, tegafur*
Lung non-small cell	Cyclophosphamide + doxorubicin + cisplatin Vindesine* + cisplatin	Methotrexate, etoposide*, lomustine, fluorouracil, ifosfamide*, mitomycin
Prostate	Diethylstilbestrol or other estrogens	Cyclophosphamide, doxorubicin, estramustine, megestrol acetate, fluorouracil, cisplatin
Renal**	No good choice	Vinblastine, lomustine, medroxyprogesterone, testosterone, tamoxifen
Melanoma	Dacarbazine or semustine*	Dactinomycin

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* Available only for investigational use.

** Drugs have major activity only when combined with surgical resection, radiotherapy or both (adjuvant chemotherapy).

*** Chemotherapy considered ineffective by some authorities.

TABLE II – COMMERCIALLY AVAILABLE CANCER CHEMOTHERAPEUTIC DRUGS

NOTE: MAJOR OR DOSE-LIMITING EFFECTS ARE IN BOLD TYPE

Drug	*Acute Toxicity*	*Delayed Toxicity*
ALKYLATING AGENTS		
Busulfan (*Myleran* – Burroughs Wellcome)	Nausea and vomiting; rare diarrhea	**Bone marrow depression;** pulmonary fibrosis; hyperpigmentation; cutaneous reactions; alopecia; gynecomastia; amenorrhea; menopausal symptoms; sterility; azospermia; leukemia; chromosome aberrations; cataracts; addisonian syndrome
Chlorambucil (*Leukeran*– Burroughs Wellcome)		**Bone marrow depression;** pulmonary fibrosis; leukemia; hepatic toxicity
Cyclophosphamide (*Cytoxan*–Mead Johnson)	**Nausea and vomiting**	**Bone marrow depression;** alopecia; hemorrhagic cystitis; sterility (may be temporary); pulmonary fibrosis; hyperpigmentation; secondary malignancies; nonspecific dermatitis; hyponatremia
Estramustine phosphate sodium (estracyt; *Emcyt* – Roche)	Nausea and vomiting, diarrhea	Mild gynecomastia; increased frequency vascular accidents; myelosuppression (uncommon); edema; dyspnea
Mechlorethamine (nitrogen mustard; HN2; *Mustargen* – Merck)	**Nausea and vomiting;** local reaction and phlebitis	**Bone marrow depression;** alopecia; diarrhea; oral ulcers
Melphalan (1-phenylalanine mustard; *Alkeran*– Burroughs Wellcome)	Mild nausea; hypersensitivity reactions	**Bone marrow depression** (especially platelets); possible pulmonary fibrosis; interstitial pneumonitis; leukemia
Thiotepa (triethylenethio-phosphoramide; *Thiotepa* – Lederle)	**Nausea and vomiting;** local pain	**Bone marrow depression;** menstrual dysfunction; interference with spermatogenesis
ANTIMETABOLITES		
Cytarabine HCl (cytosine arabinoside; *Cytosar-U* – Upjohn)	**Nausea and vomiting;** diarrhea; anaphylaxis	**Bone marrow depression;** megaloblastosis; oral ulceration; hepatic damage; fever; iritis; conjunctivitis; pulmonary edema (at very high doses)
Floxuridine (*FUDR* – Roche)	**Nausea and vomiting;** diarrhea	**Oral and gastrointestinal ulceration; bone marrow depression;** pigmentation; alopecia; dermatitis
Fluorouracil (5-FU; *Fluorouracil* – Roche; *Adrucil* – Adria)	**Nausea and vomiting;** diarrhea	**Oral and GI ulcers; bone marrow depression;** increased lacrimation; neurological defects, usually cerebellar; pigmentation; alopecia; dermatitis
Mercaptopurine (6-MP; *Purinethol* – Burroughs Wellcome)	**Nausea and vomiting;** diarrhea	**Bone marrow depression; cholestasis and rarely hepatic necrosis; oral and intestinal ulcers;** anorexia
Methotrexate (MTX; *Methotrexate* – Lederle; *Mexate* – Bristol)	**Nausea and vomiting;** diarrhea; fever; anaphylaxis	Oral and gastrointestinal ulceration, perforation may occur; **bone marrow depression;** hepatic toxicity including cirrhosis and acute hepatic necrosis; renal toxicity; pulmonary infiltrates; osteoporosis; chills, fever; alopecia; depigmentation; cutaneous reactions; infertility; menstrual dysfunction
Thioguanine (6-TG; *Tabloid Brand Thioguanine* – Burroughs Wellcome)	**Occasional nausea and vomiting**	**Bone marrow depression;** hepatic damage; stomatitis

Drug	*Acute Toxicity*	*Delayed Toxicity*
NATURAL PRODUCTS		
Asparaginase (*Elspar* – Merck)	**Nausea and vomiting; fever,** chills; headache; **hypersensitivity, anaphylaxis;** abdominal pain; hyperglycemia leading to coma	CNS depression or hyperexcitability; acute hemorrhagic pancreatitis; coagulation defects; renal damage; hepatic damage
Bleomycin (*Blenoxane* – Bristol)	**Nausea and vomiting; fever;** anaphylaxis and other allergic reactions	**Pneumonitis and pulmonary fibrosis; cutaneous reactions;** stomatitis; alopecia; hyperpigmentation; Raynaud's phenomenon
Dactinomycin (actinomycin D; *Cosmegen* – Merck)	**Nausea and vomiting;** diarrhea; local reaction and phlebitis	**Stomatitis; oral ulceration; bone marrow depression;** alopecia; folliculitis
Daunorubicin (Daunomycin; *Cerubidine* – Ives)	**Nausea and vomiting;** diarrhea; red urine (not hematuria); severe local tissue damage and necrosis on extravasation; transient EKG changes	**Bone marrow depression; cardiotoxicity** (may be irreversible); alopecia; stomatitis; cutaneous toxicity; anorexia; diarrhea; fever and chills
Doxorubicin (*Adriamycin* – Adria)	**Nausea and vomiting;** red urine (not hematuria); severe local tissue damage and necrosis on extravasation; diarrhea; transient EKG changes; ventricular arrhythmia	**Bone marrow depression; cardiotoxicity** (may be irreversible); alopecia; stomatitis; cutaneous toxicity; anorexia; diarrhea; fever, chills; urticaria; anaphylaxis; conjunctivitis; lacrimation
Mithramycin (*Mithracin* – Miles)	**Nausea and vomiting;** diarrhea; fever	**Hemorrhagic diathesis; bone marrow depression** (thrombocytopenia); coagulation abnormalities; hepatic damage; hypocalcemia and hypokalemia; stomatitis; cutaneous reactions
Mitomycin (*Mutamycin* – Bristol)	**Nausea and vomiting;** local reaction if extravasation; fever	**Bone marrow depression** (cumulative); stomatitis; alopecia; pulmonary fibrosis; hepatotoxicity and renal toxicity at high doses
Vinblastine sulfate (*Velban* – Lilly)	**Nausea and vomiting:** local reaction and phlebitis if extravasation	**Bone marrow depression;** alopecia; stomatitis; loss of deep tendon reflexes; jaw pain; paralytic ileus; inappropriate ADH secretion
Vincristine sulfate (*Oncovin* – Lilly)	Local reaction if extravasation	**Peripheral neuropathy** (loss of deep tendon reflexes, numbness, tingling and muscle weakness); neuritic pain; alopecia; mild bone marrow depression; constipation; paralytic ileus; inappropriate ADH secretion
OTHER SYNTHETIC AGENTS		
Carmustine (BCNU; *BiCNU* – Bristol)	**Nausea and vomiting;** local phlebitis	**Delayed leukopenia and thrombocytopenia** (may be prolonged); pulmonary fibrosis (may be irreversible); delayed renal damage; gynecomastia; reversible liver damage
Cisplatin (Cis-Diamminedichloroplatinum; Cis-DDP; *Platinol* – Bristol)	**Nausea and vomiting;** anaphylactic reactions; fever	**Renal damage;** bone marrow depression; ototoxicity; hemolysis; hypomagnesemia; peripheral neuropathy; hypocalcemia; hypokalemia
Dacarbazine (DTIC; DIC; *DTIC-Dome* – Miles)	**Nausea and vomiting;** diarrhea; anaphylaxis; pain on administration; flu-like syndrome	**Bone marrow depression;** alopecia; renal impairment; hepatic necrosis; facial flushing, paresthesia; rash; photosensitivity
Hydroxyurea (*Hydrea* – Squibb)	**Nausea and vomiting;** allergic reactions to tartrazine dye	**Bone marrow depression;** hyperkeratosis and hyperpigmentation; stomatitis; dysuria; alopecia; rare neurological disturbances
Lomustine (CCNU; *CeeNU* – Bristol)	**Nausea and vomiting**	**Delayed (4 to 6 weeks) leukopenia and thrombocytopenia** (may be prolonged); transient elevation of transaminase activity; neurological reactions; pulmonary fibrosis

Drug	*Acute Toxicity*	*Delayed Toxicity*
OTHER SYNTHETIC AGENTS *(Continued)*		
Mitotane (o,p′-DDD; *Lysodren* – Bristol)	**Nausea and vomiting;** diarrhea	**CNS depression;** dermatitis; visual disturbances; adrenal insufficiency; brain damage with long-term high dosage; hematuria, hemorrhagic cystitis, albuminuria; hypertension; orthostatic hypotension
Procarbazine HCI *(Matulane* – Roche)	**Nausea and vomiting;** CNS depression; Antabuse-like effect with alcohol	**Bone marrow depression;** stomatitis; dermatitis; peripheral neuropathy; pneumonitis; secondary malignancies
Streptozocin (streptozotocin; *Zanosar* – Upjohn)	Nausea and vomiting; local pain; chills	Renal damage; hypoglycemia; hyperglycemia; liver damage; diarrhea; bone marrow depression (uncommon); fever; eosinophilia
HORMONES		
Estrogens		
Diethylstilbestrol (DES; many manufacturers)	**Nausea and vomiting;** cramps	**Fluid retention;** hypercalcemia; feminization; uterine bleeding; if given during pregnancy, may cause vaginal carcinoma in offspring; increased frequency of vascular accidents
Ethinyl estradiol *(Estinyl* – Schering; others)		**Fluid retention;** hypercalcemia; feminization, uterine bleeding; increased incidence of vascular accidents
Androgens		
Dromostanolone propionate *(drolba*–Lilly)		**Fluid retention, masculinization;** hypercalcemia
Fluoxymesterone *(Android-F* – Brown; *Halotestin* – Upjohn)		**Fluid retention; masculinization;** cholestatic jaundice; hypercalcemia; painful hypertrophy of clitoris; hirsutism
Testolactone (Teslac – Squibb)	Local pain, inflammation at injection site	Hypercalcemia; rare alopecia; masculinization (minimal)
Testosterone proprionate (many manufacturers)		**Fluid retention; masculinization;** hypercalcemia
Progestins		
Hydroxyprogesterone caproate *(Delalutin* – Squibb; others)	Local abscess, pain	Hypercalcemia; cholestatic jaundice
Medroxyprogesterone acetate *(Provera* – Upjohn; others)	Orally: nausea (rare) IM: local pain, abscess at injection site	Fluid retention; hypercalcemia
Megestrol acetate *(Megace* – Mead Johnson; *Pallace* – Bristol)	Allergic reactions to tartrazine dye	Fluid retention; thromboembolism; alopecia; carpal tunnel syndrome
Corticosteroids		
Prednisone or prednisolone		Mental aberrations; gastric ulcers; glucose intolerance; osteoporosis; hypertension; cataract formation; Cushingoid features; metabolic abnormalities; myopathy
Antiestrogen		
Tamoxifen citrate *(Nolvadex* – Stuart)	Nausea and vomiting; hot flashes; transient increased bone or tumor pain	Vaginal bleeding and discharge; rash; hypercalcemia; retinopathy; corneal changes; decreased visual acuity; peripheral edema; depression; dizziness; headache

Drug	*Acute Toxicity*	*Delayed Toxicity*
HORMONES *(Continued)*		
Adrenal suppressant		
Aminoglutethimide *(Cytadren* – Ciba)	Skin rash; drowsiness; nausea; dizziness	Hypothyroidism (rare); bone marrow depression; fever; hypotension; masculinization

TABLE III – SOME INVESTIGATIONAL DRUGS

NOTE: MAJOR OR DOSE LIMITING EFFECTS ARE IN BOLD TYPE

Drug	*Acute Toxicity**	*Delayed Toxicity**
Amsacrine (AMSA; 4′-(9-acridinylamino); methanesulfon-m-anisidide; Bristol, Parke-Davis)	Nausea and vomiting; diarrhea; pain or phlebitis on infusion	**Bone marrow depression**; hepatic injury; convulsions; stomatitis; ventricular fibrillation, alopecia
Bisantrene (ADC, ADAH; Lederle)	Nausea and vomiting; hypotension; flu-like illness	Leukopenia; thrombocytopenia; phlebitis
Azacitidine (ladakamycin; Upjohn)	**Nausea and vomiting**; diarrhea; fever	Leukopenia (may be prolonged); thrombocytopenia; hepatic damage; rash; muscle pain and weakness; bone marrow depression; possibly cardiotoxicity
Etoposide (VP16-213; *Vepesid* – Bristol)	**Nausea and vomiting**; diarrhea; fever	**Bone marrow depression**; alopecia; peripheral neuropathy; allergic reactions
Hexamethylmelamine (HMM)	**Nausea and vomiting**	**Bone marrow depression**; CNS depression; peripheral neuritis; visual hallucinations
Ifosfamide *(Ifex* – Mead Johnson)	**Nausea and vomiting**	**Bone marrow depression; hemorrhagic cystitis**; alopecia; sterility (may be temporary)
Mitobronitol (dibromomannitol; DBM; *Myelobromol*–Sinclair, UK)	GI disturbances	**Bone marrow depression**; skin pigmentation; alopecia
Mitolactol (dibromodulcitol; NFN; elobromol)	**Mild nausea**	**Bone marrow depression**
Mitoxantrone HCI (DHAD; *Novantrone* – Lederle)		**Bone marrow depression**; possible cardiotoxicity
Semustine (methyl-CCNU; Bristol)	Nausea and vomiting	Delayed leukopenia and thrombocytopenia (may be prolonged); pulmonary fibrosis; leukemia; renal failure (especially in children or with large total doses)
Tegafur (ftorafur; Mead Johnson)	Nausea and vomiting; CNS symptoms including dizziness and lethargy	Stomatitis; bone marrow depression; pigmentation; alopecia; dermatitis
Teniposide (VM-26; Bristol)	Nausea and vomiting; diarrhea; phlebitis	Bone marrow depression; alopecia; peripheral neuropathy
Vindesine sulfate *(Eldisine* – Lilly)	Local reaction if extravasation; fever; nausea and vomiting; diarrhea	Bone marrow depression; alopecia; peripheral neurophathy; jaw pain; rash

*Information is preliminary; additional or more severe adverse effects may be reported.

Current Medicolegal Issues

THE CITATION–AMA

Hospital's Exclusive Contract Violates Antitrust Statutes

A hospital's exclusive contract with an anesthesiology group was an illegal tying arrangement, a federal appellate court in Louisiana ruled.

A board-certified anesthesiologist applied for admission to the medical staff of a hospital. In 1977, despite favorable recommendations by both the credentials committee and the medical staff executive committee, the hospital board voted to deny him staff privileges. The denial was based on an exclusive contract the hospital had with an anesthesiology group. The four anesthesiologists in the group supervised the nurse-anesthetists in the hospital's 13 operating rooms.

The rejected anesthesiologist then filed an action against the hospital, alleging violation of the Sherman Antitrust Act, the state antitrust law, the due process clause of the Fourteenth Amendment and another state law. A federal trial court dismissed the action, but the federal appellate court reversed. The trial court's definition of the geographical market was erroneous because nearly one-third of the patients from the area went to the hospital. This clearly gave the hospital sufficient market power to coerce purchase of anesthesiology services from the group.

The arrangement was an illegal tying arrangement in which users of the hospital's operating rooms were forced to use the hospital's chosen anesthesiology group. The hospital made a large profit from the arrangement because a small group of anesthesiologists supervised a larger group of lower paid anesthetists. However, the patients were billed for the services of an anesthesiologist.

Noting the anticompetitive effects of the exclusive contract, the court said that it prohibited competition from other groups and eliminated the surgeon's or patient's choice of anesthesiologist at the hospital.

"This opinion," the court concluded, "does not test the limits of access to staff privileges. Certainly, the staff size of each hospital is bounded by legitimate concerns of overcrowding, overtaxing of hospital personnel and resources, and the consequent decline in quality of patient care. In the instant case, however, it was not the size of the department which concerned the hospital board, but the profit which the current structure generated. In addition, the concerns which allegedly led to the implementation of the exclusive contract can be addressed by much less restrictive alternatives. They furnish an illusory basis for depriving a physician of the right to practice his profession."

The court ordered the hospital to grant the anesthesiologist staff privileges and permit him to practice his chosen profession.—*Hyde v. Jefferson Parish Hospital District No. 2,* 686 F.2d 286 (C.A.5, La., Sept. 20, 1982)

Editor's Note: A prior decision in this case was reported in THE CITATION, Vol. 42, No. 12, p. 138.

Orthopedist Sued For Alleged Negligent Misrepresentation

A trial court should have submitted a patient's claim against an orthopedic surgeon for alleged negligent misrepresentation to the jury, the Colorado Supreme Court ruled.

The patient fractured his ankle when thrown from a horse in March 1973. A physician reduced the fracture and inserted a screw into the ankle. Severe arthritis developed in the joint, and he recommended an ankle fusion. The patient sought a second opinion from another orthopedic surgeon. He agreed, but suggested first removing the screw to alleviate pain. The screw was removed but removal furnished only temporary relief. The patient then returned to the first surgeon and consented to a total ankle replacement.

Unfortunately, after the implantation of the artificial ankle, the ankle and surrounding tissue became infected. Treatment with antibiotics was unsuccessful, and the ankle was removed. The physician made four attempts to fuse the ankle, but all were unsuccessful because of the persistent infection. The patient then consulted a third surgeon, who amputated his leg below the knee on July 19, 1976.

The patient filed suit against the physician who inserted the ankle implant. The complaint was based on lack of informed consent to the surgery and on negligent misrepresentation. The trial court submitted the case to the jury only on the claim of lack of informed consent. The jury returned a verdict for the physician, and the patient appealed.

On appeal, the Supreme Court affirmed the verdict for the physician on the informed consent claim. However, it remanded the case for a new trial on the negligent misrepresentation count. The evidence established that the physician had falsely told the patient that he had participated in ankle replacement surgery when, in fact, it was his first such operation. He assured the

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patient that his concern about the possibility of amputation was unfounded, the court noted. Those statements were sufficient to raise a jury question on his negligent misrepresentation claim, the court said.—*Bloskas v. Murray,* 646 P.2d 907 (Colo.Sup.Ct., June 7, 1982; as modified, June 28, 1982)

Patient Claims Demerol Dependence Is Due To Malpractice By Physician

A trial court should not have granted summary judgment for a physician who allegedly caused a patient to become dependent on Demerol, a Texas appellate court ruled.

The patient sued her physician for damages because, she said, she became psychologically and physically dependent on Demerol which had been injected for back pain. She claimed that the physician's treatment was contrary to proper and reasonably prudent medical practice and was a proximate cause of her injury. She stated that she became dependent on the drug in August 1977.

On his motion to dismiss, the physician contended that the claim was barred because she failed to give him 60 days' notice before suit was filed. The statute requiring notice applied only to causes of action that accrued after August 29, 1977. The patient claimed her dependency began prior to August 29, but the trial court granted summary judgment for the physician.

On appeal, the decision was reversed. There was no conclusive proof that the patient's cause of action accrued after August 29, 1977. Since there was an issue concerning the date the patient's action accrued, summary judgment was improper, the court said.—*Gregory v. Bilsing,* 633 S.W.2d 356 (Tex.Ct. of App., April 19, 1982)

No Breach Of Confidentiality By Physician In Letter To Patient's Former Wife

A physician's letter to a patient's former wife, confirming a telephone conversation held when she was married to the patient, was not an invasion of privacy or breach of a confidential relationship, a federal trial court in Missouri ruled.

The patient was hospitalized on April 17, 1979, because of numbness of his face and muscle spasms. On April 30, in a telephone conversation with the patient's wife, the physician said that the patient was very tense and was overusing alcohol, nicotine, and caffeine.

The marriage ended on July 25, 1979. On September 17, the ex-wife filed a motion to reconsider custody of her son. Attached to the motion was a copy of a letter she had requested, dated August 16, in which the physician reiterated what he had told her over the phone on April 30.

The patient sued the physician for invasion of privacy and breach of confidential relationship. He claimed that release of the information in the letter without his consent was an invasion of his privacy.

The court found that because the letter was sent only to the ex-wife, the disclosure was insufficient to satisfy the publicity requirement of an invasion of privacy case involving alleged public disclosure of private facts. The court further said that such disclosure could not be said to be an unreasonable disclosure of the patient's private affairs to persons who had no legitimate interest. The letter merely confirmed a conversation held when the patient and his ex-wife were married, and the physician was entitled to discuss the patient's condition with her at that time, the court said.

As to the breach of confidential relationship allegation, the patient said that the physician was under a duty not to cooperate with his adversary in litigation. The court pointed out that the physician clearly did not seek to aid the ex-wife, as the letter stated that he did not intend "to take sides in a family conflict" and only reiterated what he had said earlier. The court granted summary judgment to the physician.—*Mikel v. Abrams,* 541 F.Supp. 591 (D.C., Mo., June 18, 1982)

Suit Filed 44 Years After X-radiation That Caused Cancer Is Barred

The statute of limitations barred a malpractice suit brought by a woman who discovered in 1978 that her cancerous thyroid was due to X-radiation therapy she received in 1936, an Illinois appellate court ruled.

The patient was treated with X-radiation therapy because of an enlarged thymus when she was an infant, in 1936. In March 1978, when her cancerous thyroid was removed, she learned that the cancer was a result of the X-radiation therapy.

In March 1980, the patient filed suit against the hospital where she was born and treated. The trial court granted the hospital's motion to dismiss.

On appeal, the patient raised the issue of whether the statute of limitations should be applied to abrogate the discovery rule in the case of a slowly developing disease in which the symptoms did not appear within an applicable limitation period and whether the limitation was retroactively applied to terminate a cause of action without giving the patient a reasonable amount of time to file suit.

The limitations act provided that no action could be filed more than two years after a party knew or should have known of an injury but in no event more than four years after the date on which the alleged injurious act occurred. In the present case, liberally constructing the act, the patient had until she reached majority (18 years) plus four years to file suit, which would be 1958.

The court therefore found that the patient's case was not filed within the prescribed period and affirmed the judgment of the trial court.—*Muller v. Health & Hospital Governing Commission of Cook County,* 436 N.E.2d 26 (ILL.App.Ct., May 6, 1982; rehearing denied, June 9, 1982)

Conviction Of Caseworker For Failure To Report Child Abuse Reversed By Court

The conviction of a supervisor of caseworkers for failure to properly respond to a report of suspected child abuse was reversed by the Colorado Supreme Court.

A 7-year-old girl had previously been placed in the custody of the county social services department after being determined to be a neglected and dependent child. In September 1976, legal custody was restored to her mother under supervision of the department. The child's stepfather was uncooperative and refused to permit a caseworker to visit the home.

In November, a school nurse who suspected child abuse consulted the school principal, who talked to the mother and advised the supervisor of his suspicions. The supervisor and a caseworker under his supervision talked with the child's mother, but neither personally visited the child from September 1976, until she died, in early January 1977, under circumstances suggesting child abuse.

The supervisor was charged with second-degree official misconduct because of failure to perform his duty of supervising the child and making direct personal contact with her after receiving a report of child abuse. The supervisor contended that he was justified in believing that the child was not in immediate danger because the mother and stepfather had indicated that they would cooperate. He was convicted by a jury.

On appeal, the supervisor contended that the statute under which he was convicted was void for vagueness and that the indictment by which he was charged was insufficient. The court found that the first basis for criminal responsibility under the statute, that he refrained from performing a "duty imposed upon him by law," was not unconstitutionally vague. However, the alternate statutory basis, that he refrained from performing a duty "clearly inherent in the nature of his office," provided no readily ascertainable standards by which conduct could be measured, the court said.

The court said that an indictment under the statute must set out the source of duty imposed by law that was not performed. The court found that the supervisor was not given effective notice of the crime charged and therefore not afforded adequate opportunity to prepare a defense.—*People of the State of Colorado v. Beruman,* 638 P.2d 789 (Colo.Sup.Ct., Jan. 11, 1982)

Osteopaths' Use Of "M.D." Barred In Texas

Texas could bar osteopaths from using the designation "M.D." after their names, a federal appellate court for Texas ruled.

Adopting a trial court's opinion, the appellate court ruled against two osteopaths who sued the State Board of Medical Examiners. They claimed that forcing them to use the designation "D.O." subjected them to prejudice, antipathy, and loss of earnings. They noted that the requirements for licensure of "D.O." and "M.D." degree holders were identical.

The court said that the licensing scheme had a rational basis in requiring physicians to hold themselves out under the professional degree that they earned. The osteopaths claimed violation of their equal protection rights because graduates of foreign medical schools who have degrees which do not translate to doctor of medicine or something similar can be licensed as M.D.'s. The court observed that schools of osteopathy were virtually an American phenomenon. What set them apart from M.D.'s, manipulative therapy training, also set them apart from graduates of foreign medical schools as well, the court said.—*Maceluch v. Wysong,* 680 F.2d 1062 (C.A.5, Tex., July 21, 1982)

Credentials Committee Records Cannot Be Subpenaed

A patient could not obtain records from a medical center's credentials committee that investigated an operation performed on her by a dentist, a Delaware trial court ruled. The patient subpenaed the center's file on the operation and the notes, memoranda, records, correspondence, reports and photographs relating to an investigation conducted by the center's credentials committee concerning that operation. The center opposed production of the records of the credentials committee but did not oppose production of the medical records pertaining to the operation. The court said that the records of the credentials committee were confidential by statute and could not be subpenaed.—*Danklef v. Wilmington Medical Center,* 429 A.2d 509 (Del.Sup.Ct., March 26, 1981)

The President's Page

Prospective Payments, Part II

The business coalition has proposed an all payer prospective plan as the cornerstone of its six point health cost management plan. This is being transformed into a bill which they intend to present to the state legislature for passage in the 1984 session. At the same time, meetings and conferences are being held in various parts of the state by interested parties, discussing issues which the business group feels they have already resolved. This prospect of hospital regulation, with the likelihood of physician regulation to follow, is, I believe the single most important issue facing medicine today. There is no question that health care purchasers, namely the federal government and private business are determined to regulate the delivery of health care in this country as the only method to reduce health costs. It is somewhat ironic that while the business community had embraced the concept of competition as the answer for containing rising health care costs, i.e. HMO's, IPA's, and PPO's, they have now about-faced and are striving to utilize their industrial clout to regulate the health care industry.

At the present time, the main protagonists in our state are the Connecticut Hospital Association vs. the CBIA. Physicians interested in not only cost containment but also quality of health care have a vital stake in this confrontation and cannot afford to sit idly by while the issues are decided. Industry has mobilized its formidable resources on the legislative front. Armed with consultants in the legal, public relations, and health care fields, aided by economists industrial relations experts, and lobbyists with almost unlimited funds, they represent a formidable opponent.

To allow the CBIA's all-payer prospective payment system to be passed by the state legislature is not only frought with uncertainties as to its cost effectiveness, but can prove to be disastrous to the quality of health care delivery. The federally funded DRG's have been in effect only since October 1983, and serious problems regarding intensity of services for similar groupings has already become apparent. The CPRO which was incorporated as recently as May 1983, could make a significant impact in containing costs, but, it has not yet had an opportunity to demonstrate its effectiveness. If the business coalition is indeed sincere in its desire to work as a catalyst for all concerned parties, then their first priority would be to refrain from implementing the statewide health care program that they have formulated unilaterally.

As President of the Connecticut State Medical Society, I pledge to mobilize our resources and to cooperate with truly interested parties in addressing and resolving this pressing problem of containing the rising cost of health care, while at the same time, ensuring that quality is not compromised.

Daniel W. Doctor, M.D.
President

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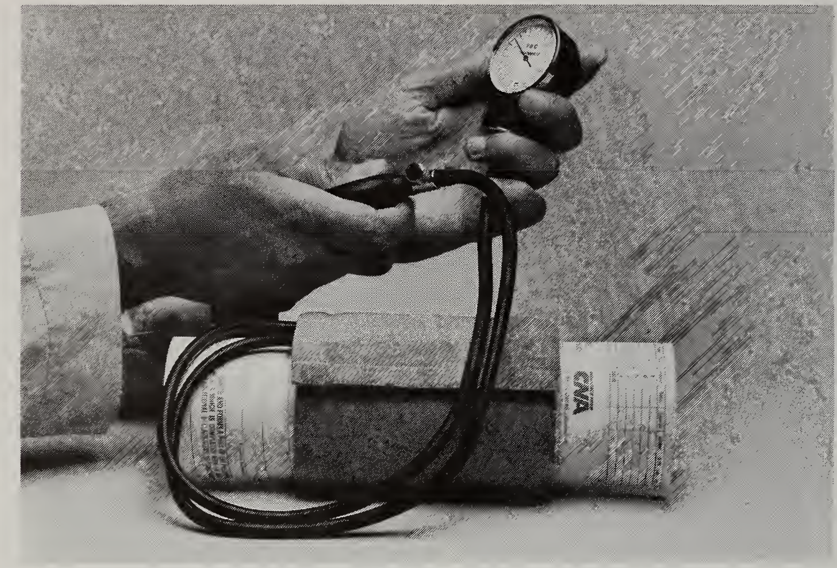

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Reflections From the Dean's Office

Harmless Obsessions

ROBERT U. MASSEY, M.D.

Many of us who are closer to his generation will recall Osler's "two fixed ideas well known to my friends, harmless obsessions with which I sometimes bore them, — The first is the comparative uselessness of men above forty years of age. — My second fixed idea is the uselessness of men above sixty — ." He noted in jest Anthony Trollope's description in his novel, *The Fixed Period,* of "the remarkable scheme of a college into which at sixty, men retired for a year of contemplation before a peaceful departure by chloroform."

Osler was 55, and this was his valedictory as a member of the faculty of Johns Hopkins University;[1] he and his colleagues were having serious fun, of course, but a new verb had entered the language: "to Oslerize." Newspaper headlines proclaimed that OSLER RECOMMENDS CHLOROFORM AT SIXTY, and he found himself in hot water, "super heated," according to one observer.[2] Later in the same address, "The Foundations of a University Education," he said:

> "As it can be maintained that all great advances have come from men under forty, so the history of the world shows that a very large proportion of the evils may be traced to the sexagenarians — nearly all the great mistakes politically and socially, all the worst poems, most of the bad pictures, a majority of the bad novels, not a few of the bad sermons and speeches."

Several of us, already arrived at the age for Oslerization, were lightheartedly discussing how the world looked from the down slope of the hill. According to one of his biographers, Trollope at sixty-one had begun to feel the shadows closing in, although he lived on to be sixty-eight; Osler passed his three score years and ten by six months. In those years of the late nineteenth and early twentieth century, the horizon was closer for someone at sixty than it is now. Life expectancy has increased by twenty years. We spoke of that but were not sure that it made much difference in how it felt to be healthy and sixty; we had all sensed the horizons with their hint of a shoreline, or of land not far beyond. It was a feeling of limits, comforting when you got used to it. For the first time there was a certainty about time having an end; that meant a consciousness that there would be things now that you would never do: best to forget them. There were other things that you would have to make room for; you would have to stop doing unsatisfying things and reading anything which would likely be forgotten by you in a day and by the world in a year. That could mean missing out on some brilliant work, but serious choices are rarely easy. Osler speaks of the "waxen tablet of memory" becoming "hard and crowded." Knowing that would help with the choices: if it takes more work to get something engraved in the hard wax, it had better be worthwhile.

My sample was a small group of academics, mostly physicians, but they made remarkably similar observations about life in the seventh decade, a few having to do with physiology. No one thought much of the "harmless obsessions" for himself but could name some candidates. Even Osler later admitted that "Whether Anthony Trollope's suggestion of a college and chloroform should be carried out or not I have become a little dubious, as my own time is getting so short." On the other hand no one thought much about research on the aging process either; the inherited span seemed long enough, and then only if all the major systems remained reasonably intact. And no one wanted to be young again, not even to do a decade over.

The sampling was too limited, but I suspect we ought to be asking questions of those who in ancient Rome would have been called *Depontani* (because, as Osler suggests, they were thrown from the bridge to keep them out of the senate!). We are making all sorts of policy decisions about the *sexagenarii* and those beyond; before our policy deciders and professional opinion makers have their way, they should find out whether longevity is what we really want! Several years after the chloroform remarks, Osler wrote: " — the discussion which followed my remarks has not changed, but has rather strengthened my belief that the real work of life is done before the fortieth year and that after the sixtieth year it would be best for the world and best for ourselves if men rested from their labors."

REFERENCES

1. February 22, 1905.
2. Cushing H: The Life of Sir William Osler, Oxford University Press, p 669, 1940.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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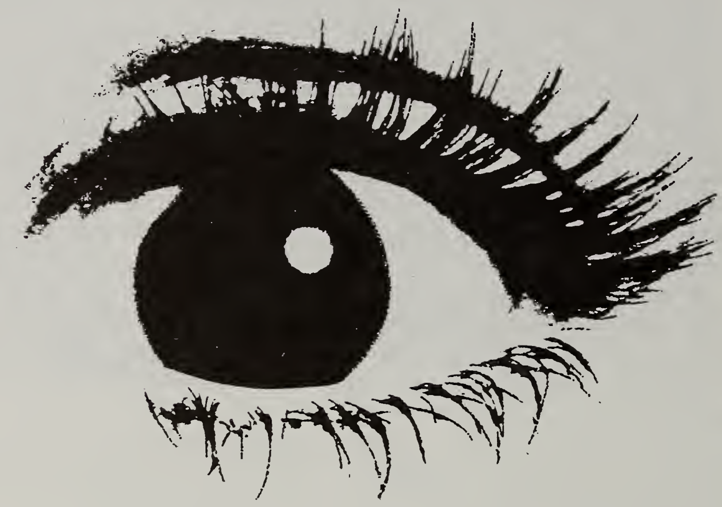

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Editorial

Ethical Implications of Clinical Judgment
(The Role of the Hospital Bioethic Committee)

Not much more than a decade ago such an article would be regarded as unnecessary and considered to be an intrusion of physicians' prerogatives in patient care. Today, it is obligatory in view of the emergence of the intrusions of the courts, the state legislatures, the legal profession, the Federal bureaucrats and even the United States Congress into the ever expanding controversies regarding the patient's right to live and the right to die.

Many landmark court cases during the past ten or twelve years pertaining to bioethical issues involving handicapped newborns and terminally ill or prognostically bad other patients have caused ethicists, physicians, attorneys, judges, patients and their families, the clergy and society at large to rightfully demand that the health professions come forth and develop a mechanism or a process which could give assistance to all concerned in resolving these painful issues.

The past two decades have seen many striking medical advances in life-saving and life-prolonging technology. At the same time these achievements have brought forth complex problems and raised many troubling issues such as what are the limits of technology and available resources and what are the rights of the terminally ill patient and those of the impaired infant.

The question most asked recently has been that of where does the physician, the patient or the family go for assistance when these controversial cases arise? The American Medical Association, The American Hospital Association, many state medical associations, and even the recently disbanded President's Commission for the Study of Ethical Problems have agonized over the question and have offered some suggestions and proposals. Most of the aforementioned groups agree that since the great majority of these problem cases occur in the hospitals, the hospitals offer the best source of assistance.

I am in total agreement with this last statement and have been a long time advocate of the hospital-based bioethics committee and as more time passes and more cases emerge requiring court or governmental intervention, I am more firmly convinced that every hospital in this nation should establish such a committee. The question now is how soon can this be accomplished? The answer—as soon as each hospital recognizes the importance of this concept, writes the proper by-laws provision in the medical staff by-laws for its legitimacy, promulgates the guidelines for the committee protocol, and defines the roles, responsibilities, and composition of the committee. Hospitals should be informed that in the vast majority of states in this nation such committees are qualified for immunity from discovery in legal searches for evidence and professional liability cases and for the other legal safeguards afforded committee members participating in decisions regarding the quality of patient care.

One such hospital in my experience has demonstrated great success in this endeavor. I refer to the French Hospital and Medical Center, a community, acute-care hospital in San Francisco, California. When faced with several complicated cases demanding immediate decisions, the medical staff established a bioethics committee and promulgated the following stipulations regarding its functions, composition, structure, etc.:

1. First and foremost, it shall be a medical staff committee with open access to all parties involved in any specific case. The composition of the committee shall consist of
    a. At least four physician members of the active medical staff with representation from the major departments
    b. A representative from the Chaplain's office or from the local clergy
    c. A representative from the medical staff or governing board's legal counsel
    d. A representative from the nursing staff
    e. A representative from the social services department

2. The committee shall meet at least quarterly for general discussions on bioethical issues and for the purpose of providing guidance to the medical staff on these issues.
3. A subcommittee shall be appointed and be available on 24 hours' notice to convene and offer assistance on any specific case or cases. This subcommittee shall have five members, three of whom shall be physicians and two nonphysicians. (The physician members should have expertise in the medical aspects of the specific case or cases).
4. The subcommittee shall deal with the following cases:
    a. The withholding of care
    b. The initiating of expensive diagnostic and therapeutic programs in cases where it has been established that the prognosis is poor
    c. Cases in which the attending physician has a disagreement with other physicians in the case
    d. Cases in which there is a disagreement between the family or the patient with the attending physician
    e. Cases in which there is a disagreement between the attending physician and the rules and regulations previously established by the medical staff.

Requests for referrals to the subcommittee may be made to the medical staff office or directly to the Chairperson of the Bioethics Committee. When such a request for referral is made to the committee by others than the attending physician, the chairman shall immediately contact that physician and invite him or her to the meeting.

The following may make requests for referral:
The attending physician or other physicians involved
A member of the nursing staff or social services staff
The hospital Chaplain or the family's clergy
The family and/or the patient

The foregoing protocol in use at French Hospital has been implemented and is accepted by the staff and the many others concerned with the care of patients presenting complicated problems.

It is a beginning and may need refinements and modifications in the future. Whether its deliberations will serve to keep the lawyers, the courts, and the government off the backs of the physicians, patients, and/or family remains to be seen. Hopefully, it will. If any other hospital wishes to adopt its modus operandi, French Hospital graciously gives its consent. I give my blessings and encouragement to do so and as rapidly as possible.

In conclusion, I call attention to a condition which has become prevalent in this country. It is called "hyperlexis"—too much law. The sad part is that although many of the legal problems in patient care have come about from the activities of unhappy or confused patients and/or their families, and the attorneys involved, a new wave of this epidemic of "hyperlexis" has been set off by physicians themselves. Although the final decisions regarding resolution of these difficult cases involving the right to live and the right to die must be made by the patient and/or family, the physician is considered to be a key factor in the decision-making process. "Hyperlexis" often alters the judgment of the physician or in some cases causes him or her to refrain from offering objective advice. The hospital bioethics committee should alleviate this and act as an antidote to "Hyperlexis."

Samuel R. Sherman, M.D.

San Francisco, California
Chairman, American Medical Association, Judicial Council

Diagnosis of Extrahepatic Obstructive Jaundice

The precise diagnosis of extrahepatic biliary obstruction is based on a complex set of information derived from clinical evaluation, routine laboratory studies, and advanced radiographic techniques. Some of the tests are administered in various sequences, which may affect the speed with which the correct diagnosis is made. Using decision analysis and computer evaluation, Richter et al compared the accuracy, sensitivity, specificity, invasiveness, and cost of 10 diagnostic strategies.

The following three strategies were found to have the best results:

1. Ultrasonography first. This strategy uses ultrasonography as a screening procedure. The subsequent sequence of tests if results are abnormal is transhepatic cholangiography, endoscopic retrograde cholangiopancreatography, and liver biopsy. The diagnosis may be confirmed at any step in the strategy, but procedures continue to biopsy if clinical judgment indicates.
2. Endoscopic retrograde cholangiopancreatography first. Ultrasonography is omitted in this strategy. A normal endoscopic retrograde cholangiopancreatogram is followed by clinical observation and, if jaundice persists, a liver biopsy.
3. Selective cholangiography. The ultrasonogram is used to detect the presence of dilated ducts and to select the optimal type of cholangiography.

The sensitivity of the first strategy is lower than that of the other two because it requires two abnormal test results (ultrasonogram and cholangiogram) for a positive diagnosis. Yet its specificity is higher because multiple tests must be normal for a negative diagnosis. Since the cholangiogram is the basis of the other two strategies, their sensitivity and specificity are similar. The "ultrasonography first" strategy uses fewer invasive procedures, and the overall cost is lower.

The authors conclude that evaluation of patients with a low probability of disease should begin with ultrasonography, a noninvasive test, to limit costs and complications. In patients with a high probability of anatomic obstruction, however, use of ultrasonography first might cause a large number of diagnostic errors.

Richter JM, Silverstein MD, Schapiro R: Suspected obstructive jaundice: A decision analysis of diagnostic strategies. *Ann Intern Med* 99:46-51, 1983. From the Harvard Medical School, Boston, Massachusetts.

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Council Meeting

Thursday, December 15, 1983

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahamed, Ahrens, Beck, Bobruff, Czarsty, Doctor, Freedman, Friedberg, James, Kaess, Kamens, McDonnell, Mendillo, Orphanos, Parrella, Petrie, Ragusa, Reyelt, Jr., Sullivan, Villa, Waldron and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Sweeney, Mr. Tomat (FCMA), Mrs. Harney (NHCMA), Mrs. Clark (HCMA) and Mrs. Sandler (President, Auxiliary).

Absent were: Drs. Alisberg, Canzonetti, Concannon, Dardick, Fabro, Hess, Keefe, Sadowski, Sharon, Sweet, and Whalen, Jr.

Reports from Physicians Serving on State and Federal Agencies

Dr. Eslami reported on the status of Certificate-of-Need (CON) review of "imaging equipment" in Northwest Connecticut Health Systems Agency (NWCHSA) and Connecticut in general.

Mr. Fiorentino briefly summarized his report drawing particular attention to the Medicare proposals in the House and Senate as well as activities to reauthorize the health planning program.

In conjunction with this, Mr. Fiorentino detailed his report (placed on the table) on the first meeting of the Long Term Care Task Force sponsored by the Statewide Health Coordinating Council (SHCC) which met in November. The Task Force has been formed to refine and clarify "Planning Guidance #7 1990 Nursing Home Bed Need Projection by Region," and report back to SHCC October, 1984. After reviewing the report, the Council responded to the SHCC request by voting to appoint Dr. Archie Golden, Wethersfield, as the Society designee on the Task force.

Report of the President

Daniel W. Doctor, M.D., reported on his attendance at a recent CNA advisory Board meeting. He indicated to the Council that CNA planned territorial rates for October, 1984, and mentioned that the loss control teaching program were reported to be very successful.

Report on the AMA Convention

A written summary of actions was distributed at the meeting and individual members of the CSMS-AMA delegation gave verbal reports on the convention activities. A more detailed report on the AMA Convention will be published subsequently in *Connecticut Medicine.*

It was also pointed out that the AMA House of Delegates had voted to allow Presidents of state medical societies to serve as alternate delegates. It was VOTED to have an amendment drawn up for the CSMS House of Delegates to incorporate in CSMS bylaws.

Liver Transplantation Resolution—Referred to Council by House of Delegates

M. Wayne Flye, M.D., Director of Organ Transplants at Yale-New Haven Hospital, discussed the issue of liver transplantations with the Council. He mentioned that three liver transplantations had been performed at Yale-New Haven in the past three months. It was mentioned that liver transplants had not been funded in Connecticut through Blue Cross/Blue Shield or other insurance mechanisms although there was an indication the BC/BS and the Department of Income Maintenance had agreed to do so at a meeting earlier in the day. The following resolution, referred to the Council by the House of Delegates, was adopted:

"RESOLVED: CSMS declare liver transplantation to be an accepted therapeutic procedure and recommend that all third party payors in Connecticut recognize liver transplantation as a reimbursable surgical procedure."

It was agreed to forward a copy of the resolution to the Department of Income Maintenance, Blue Cross/Blue Shield, other third party payors in Connecticut and the media.

Psychiatric Beds in State Hospitals

Following review of a communication received from the Connecticut Chapter of the American College of Emergency Physicians, Dr. Jay Walshon, relating to the increasing difficulty in obtaining bedspace for psychiatric patients, it was VOTED to support the views of the Connecticut Hospital/Association, the American College of Emergency Physicians and the American Psychiatric Association that there is a need for more psychiatric beds in state hospitals.

It was further VOTED that this information be forwarded to all members of the legislature, Commissioner of Mental Health, Governor, county medical associations, CSMS Committee on Mental Health, CSMS Legislative Committee, Directors of State hospitals and the media.

Request from Business Advisory Group

It was VOTED to designate Norman Alisberg, M.D., West Hartford, as the CSMS liaison person between CSMS and the Business Advisory Group to the Business Coalition on Health. An initial exploratory meeting was held on December 13th at the Lord Cromwell between members of the CBIA and CSMS staffs.

Report of Committee on Statewide Medical Planning RE: "All-Payors" Prospective Payment System

Resolution Adopted by Blue Cross/Blue Shield Board RE: "All-Payors" Prospective Payment System

Both items were considered together. Mr. Tony Martin, Vice President, Provider Affairs and Medicare Administration at Blue Cross/Blue Shield, Mr. Dennis May, President of the Connecticut Hospital Association and Mr. Joseph Coatsworth, Legislative Representative of CHA, appeared before the Council to discuss the proposed CBIA "All-Payor" system which would extend the DRG concept to all hospital patients.

It was VOTED that the CSMS, through its officers and Executive Director, act immediately, in concert with the Connecticut Hospital Association, Blue Cross/Blue Shield and any others interested, to study the possiblility of alternate, more moderate approaches in changing the financing of health care.

It was also VOTED that the CSMS Committee on Legislation be instructed to oppose with all means at its disposal the current plan of CBIA for an "All-Payor" prospective payment system. During the discussion, it was pointed out that the primary objection to the "All-Payor" system is that it represents an effort to implement an unproven methodology as of October 1984, and that more time is needed to evaluate it. It was VOTED further that the CSMS Committee on Legislation be instructed to oppose any "All-Payor" legislative proposal introduced in the 1984 legislative session.

Report of Delegate to Vermont State Medical Society

It was VOTED to accept with commendation and information the report submitted by Lawrence B. Ahrens, M.D.

Impact of Mandatory Medicare Assignment

Isadore H. Friedberg, M.D., opted to comment briefly on legislative activities rather than the Medical assignment issue. He apprised the Council that the Committee on Legislation is still attempting to work out differences in proposed legislation providing for a mechanism for physicians to report patients deemed unfit to drive. Dr. Friedberg also stressed the importance of having established Committees on Impaired Physicians functioning in the state.

Report of the Ad Hoc Committee on Tenure and Distribution of AMA Delegates

Lawrence B. Ahrens, M.D., Chairman of the Ad Hoc Committee on Tenure and Distribution of AMA Delegates, reported to the Council on the deliberations of his committee.

It was VOTED as follows:

1. That the nominating committee and preliminary selection committee shall be directed to make an effort to select one delegate and one alternate from each of the counties of Fairfield, New Haven and Hartford and one delegate and one alternate delegate from any of the five other counties in the state.
2. That tenure be limited to eight years of continuous service which may be repeated after an interval of no less than one year.
3. That alternate delegates be given priority consideration for the position of delegate whenever possible.

Appointments to AMA Councils

Council Chairman, Guy W. Van Syckle, M.D., reported on the candidacy of Robert McAfee, M.D., (Maine) for AMA Trustee. He mentioned that the election would be closely contested but that Dr. McAfee had a reasonable chance for victory.

There were no nominees for AMA Council.

Life Members

It was VOTED to accept for information the following list of Life Members:

Name	Town	Effective Date
Robert R. Berneike	Woodbridge	1/1/84
Donald T. Book	West Hartford	1/1/84
Richard W. Breck	Wallingford	1/1/84
Thomas L. Bucky	Weston	1/1/84
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(continued on p. 137)

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References:

1. Stone PH, Turi ZG, Muller JE: Efficacy of nifedipine therapy for refractory angina pectoris. *Am Heart J* 104:672-681, September 1982.
2. Antman E, Muller J, Goldberg S, et al: Nifedipine therapy for coronary-artery spasm: Experience in 127 patients. *N Engl J Med* 302:1269-1273, June 5, 1980.

BRIEF SUMMARY
PROCARDIA® (nifedipine) **CAPSULES** For Oral Use

INDICATIONS AND USAGE: I. Vasospastic Angina: PROCARDIA (nifedipine) is indicated for the management of vasospastic angina confirmed by any of the following criteria: 1) classical pattern of angina at rest accompanied by ST segment elevation, 2) angina or coronary artery spasm provoked by ergonovine, or 3) angiographically demonstrated coronary artery spasm. In those patients who have had angiography, the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina, provided that the above criteria are satisfied. PROCARDIA may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed, e.g., where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm, or when angina is refractory to nitrates and/or adequate doses of beta blockers.

II. Chronic Stable Angina (Classical Effort-Associated Angina): PROCARDIA is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents.

In chronic stable angina (effort-associated angina) PROGARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in those patients are incomplete.

Controlled studies in small numbers of patients suggest concomitant use of PROCARDIA and beta blocking agents may be beneficial in patients with chronic stable angina, but available information is not sufficient to predict with confidence the effects of concurrent treatment, especially in patients with compromised left ventricular function or cardiac conduction abnormalities. When introducing such concomitant therapy, care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs. (See Warnings.)

CONTRAINDICATIONS: Known hypersensitivity reaction to PROCARDIA.

WARNINGS: Excessive Hypotension: Although in most patients, the hypotensive effect of PROCARDIA is modest and well tolerated, occasional patients have had excessive and poorly tolerated hypotension. These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment, and may be more likely in patients on concomitant beta blockers.

Severe hypotension and/or increased fluid volume requirements have been reported in patients receiving PROCARDIA together with a beta blocking agent who underwent coronary artery bypass surgery using high dose fentanyl anesthesia. The interaction with high dose fentanyl appears to be due to the combination of PROCARDIA and a beta blocker, but the possibility that it may occur with PROCARDIA alone, with low doses of fentanyl, in other surgical procedures, or with other narcotic analgesics cannot be ruled out. In PROCARDIA treated patients where surgery using high dose fentanyl anesthesia is contemplated, the physician should be aware of these potential problems and, if the patient's condition permits, sufficient time (at least 36 hours) should be allowed for PROCARDIA to be washed out of the body prior to surgery.

Increased Angina: Occasional patients have developed well documented increased frequency, duration or severity of angina on starting PROCARDIA or at the time of dosage increases. The mechanism of this response is not established but could result from decreased coronary perfusion associated with decreased diastolic pressure with increased heart rate, or from increased demand resulting from increased heart rate alone.

Beta Blocker Withdrawal: Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina, probably related to increased sensitivity to catecholamines. Initiation of PROCARDIA treatment will not prevent this occurrence and might be expected to exacerbate it by provoking reflex catecholamine release. There have been occasional reports of increased angina in a setting of beta blocker withdrawal and PROCARDIA initiation. It is important to taper beta blockers if possible, rather than stopping them abruptly before beginning PROCARDIA.

Congestive Heart Failure: Rarely, patients, usually receiving a beta blocker, have developed heart failure after beginning PROCARDIA. Patients with tight aortic stenosis may be at greater risk for such an event.

PRECAUTIONS: General: Hypotension: Because PROCARDIA decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of PROCARDIA is suggested. Close observation is especially recommended for patients already taking medications that are known to lower blood pressure. (See Warnings.)

Peripheral edema: Mild to moderate peripheral edema, typically associated with arterial vasodilation and not due to left ventricular dysfunction, occurs in about one in ten patients treated with PROCARDIA. This edema occurs primarily in the lower extremities and usually responds to diuretic therapy. With patients whose angina is complicated by congestive heart failure, care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

Drug interactions: Beta-adrenergic blocking agents: (See Indications and Warnings.) Experience in over 1400 patients in a non-comparative clinical trial has shown that concomitant administration of PROCARDIA and beta-blocking agents is usually well tolerated, but there have been occasional literature reports suggesting that the combination may increase the likelihood of congestive heart failure, severe hypotension or exacerbation of angina.

Long-acting nitrates: PROCARDIA may be safely co-administered with nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

Digitalis: Administration of PROCARDIA with digoxin increased digoxin levels in nine of twelve normal volunteers. The average increase was 45%. Another investigator found no increase in digoxin levels in thirteen patients with coronary artery disease. In an uncontrolled study of over two hundred patients with congestive heart failure during which digoxin blood levels were not measured, digitalis toxicity was not observed. Since there have been isolated reports of patients with elevated digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing PROCARDIA to avoid possible over- or under-digitalization.

Carcinogenesis, mutagenesis, impairment of fertility: When given to rats prior to mating, nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose.

Pregnancy: Category C. Please see full prescribing information with reference to teratogenicity in rats, embryotoxicity in rats, mice and rabbits, and abnormalities in monkeys.

ADVERSE REACTIONS: The most common adverse events include dizziness or light-headedness, peripheral edema, nausea, weakness, headache and flushing each occurring in about 10% of patients, transient hypotension in about 5%, palpitation in about 2% and syncope in about 0.5%. Syncopal episodes did not recur with reduction in the dose of PROCARDIA or concomitant antianginal medication. Additionally, the following have been reported: muscle cramps, nervousness, dyspnea, nasal and chest congestion, diarrhea, constipation, inflammation, joint stiffness, shakiness, sleep disturbances, blurred vision, difficulties in balance, dermatitis, pruritus, urticaria, fever, sweating, chills, and sexual difficulties. Very rarely, introduction of PROCARDIA therapy was associated with an increase in anginal pain, possibly due to associated hypotension.

In addition, more serious adverse events were observed, not readily distinguishable from the natural history of the disease in these patients. It remains possible, however, that some or many of these events were drug related. Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2%. Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0.5% of patients.

Laboratory Tests: Rare, mild to moderate, transient elevations of enzymes such as alkaline phosphatase, CPK, LDH, SGOT, and SGPT have been noted, and a single incident of significantly elevated transaminases and alkaline phosphatase was seen in a patient with a history of gall bladder disease after about eleven months of nifedipine therapy. The relationship to PROCARDIA therapy is uncertain. These laboratory abnormalities have rarely been associated with clinical symptoms. Cholestasis, possibly due to PROCARDIA therapy, has been reported twice in the extensive world literature.

HOW SUPPLIED: Each orange, soft gelatin PROCARDIA CAPSULE contains 10 mg of nifedipine. PROCARDIA CAPSULES are supplied in bottles of 100 (NDC 0069-2600-66), 300 (NDC 0069-2600-72), and unit dose (10x10) (NDC 0069-2600-41). The capsules should be protected from light and moisture and stored at controlled room temperature 59° to 77°F (15° to 25°C) in the manufacturer's original container.

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Indications and Methods of Measurement of Intracranial Pressure

CHARLES C. DUNCAN, M.D. AND LAURA R. MENT, M.D.

Intracranial pressure (ICP) assessment has been carried out in animals and man since the latter 19th century. Leyden,[1] Key and Retizius,[2] Roy and Sherrington,[3] Hill[4] and others explored variations in brain volume. Quinctze in 1891 introduced the lumbar puncture (LP) as a clinical method with subsequent well-known use.[5] Prior to Lundgren's 1960 monograph,[6] ICP was not clinically applied or assessed in any systematic fashion other than for reducing pressure at operation or instilling gas for ventriculography. His cases and methods served as the basis for the widespread clinical application of ICP monitoring. Since that time, there has emerged an expanding literature related to ICP dynamics and the application of this information in the intensive care unit (ICU) setting. As late as 1975, there continued significant debate as to the clinical usefulness of ICP monitoring in terms of whether such measurements represent a meaningful parameter to follow in individual patients or if they should be reserved for investigation protocols. The primary aspect which led to clinical application is the finding that clinical deterioration follows ICP rises; and that if such rises are prevented, then there is a better patient outcome.[7]

The brain resides in a unique closed compartment with a significantly limited relation to increases of volume. The pressure inside this volume is determined by the container and its contents. The container is in the form of the skull and dura which represents a closed box in older children and adults. In infants and younger children, it will expand with a limited rate. Inside are obviously the brain, cerebrospinal fluid, and a certain blood volume. In pathological situations, various mass lesions may be present as well.[6] There is now extensive literature regarding the detailed physiological and pathological aspects of ICP which are beyond the context of this discussion; [8,9,10] however, several aspects are quite important to the basic management of the child with raised ICP.

Where ICP is raised there is a poor correlation between lumbar puncture pressure; and that intracranially blocks along the CSF pathways, brain shifts, leakage of fluid at puncture sites, and small ventricular volume account for most of the discrepancies as well as the potentially disastrous consequence of LP in the setting of such raised pressure. [11]

Raised ICP is a common mechanism which arises from a number of pathological processes varying from obstruction of the CSF pathways to intracranial mass lesions, as generalized brain edema. Brain injury in these processes is the result of the primary effects of the pathological process and the secondary effects of the raised ICP which will prevent adequate cerebral blood flow. If there is inadequate cerebral blood flow, further secondary injury will occur in terms of ischemic events. A cerebral perfusion pressure of 50 to 60 mm Hg is considered to be the minimal necessary level to permit adequate cerebral blood flow. Cerebral perfusion pressure (CPP) is operationally defined as the net of mean arterial blood pressure (MABP) and ICP. In the management of raised ICP, the CPP is the critical parameter followed, although raised ICP itself is hypothesized to have deleterious effects on brain.[12]

Compliance is the next important concept in dealing with raised ICP. Operationally, this is the increase in ICP resulting from the addition of a known volume to the intracranial volume—usually the injection of a volume into the ventriculostomy catheter. At normal and lower pressures, the addition of volume produces a transient rise in ICP and then returns to the baseline or previous pressure. As the pressure rises, volume injected produces progressively greater rises in ICP. The result of this from a practical standpoint is that at significantly raised pressures small changes in ventricular volume is by removing a few drops of CSF from the ventricular system or slightly changing the $PaCO_2$ may have dramatic effects on the ICP as will be discussed with management.[13]

The most significant rationale for the measurement of ICP in the ICU is that clinical deterioration occurs after rises in ICP. Thus, observing the compromised patient for further deterioration means that the damaging rises

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in ICP have already taken place by the time treatment is instituted.[14]

The indications for the measurement of ICP are those of significantly altered levels of consciousness in the face of likely raised ICP. The most usual exception to this ample formulation is the presence of a large mass with brain shifts which requires surgical removal. The usual conditions where ICP monitoring are considered are in head injury, intracranial tumor, Reye's syndrome, hypoxic-anoxic insults, meningitis-cerebritis, spontaneous intracranial hemorrhages, and certain instances in the treatment of hydrocephalus.[15]

ICP monitoring should be considered in those children in coma as defined by an objective scale who do not have a mass which requires operation. This is in distinction to current recommendations for adults with head injury in that adult patients in coma with an entirely normal computerized tomographic (CT) scan have a low incidence of raised pressure. Children on the other hand, even with normal CT scan, are at significant risk for raised pressure by "flash edema of childhood" or cerebral hyperemia.[16]

With intracranial tumor that obstructs the CSF pathways, classically tumors of the IV ventricle, ICP monitoring takes place in two situations.[17] The first is with the child who has hydrocephalus and signs of raised ICP. In this situation, ventriculostomy is placed with the patient awake and lowered to normal values prior to general anesthesia and shunt placement. The other instance is where there is not sufficient raised ICP and ventriculomegaly to require prior shunting, but ventriculostomy is placed pre- or intraoperatively for perioperative monitoring. Similar consideration apply for masses obstructing the III ventricle.

With Reye's syndrome, ICP monitoring is carried out in conditions of coma.[18] The Lovejoy Scale[19] may be difficult to apply with significant overlap in category in the signs that a particular patient may exhibit. For the past three years at the Yale-New Haven Hospital Pediatric ICU, we have applied the Glasgow Coma Scale (GCS) for patients with Reye's syndrome. Ventriculostomy has been placed when the patient has a GCS of 7 to 8 which corresponds to Grades II to III in the Lovejoy Scale. Clothing disorders are corrected with fresh frozen plasma prior to ventriculostomy placement.[20]

Children with hypoxic-anoxic insults from sudden infant death syndrome (SIDS), drowning, and similar situations have frequently undergone ICP monitoring when the patient is presented in coma. Also, patients with low perfusion syndromes either during or following cardiac surgery and in coma. Also, patients with low perfusion after cardiac surgery and in coma have undergone ICP monitoring.

With meningitis and cerebritis in patients with coma, ICP monitoring should be considered. Even in the face of pyogenic infection, cerebral perfusion must be maintained in order to have a viable situation. In the treatment of refractory shunt infections, ICP may require continuous control.

Similarly with intracranial hemorrhage such as subarachnoid hemorrhage and intracerebral hemorrhage, ICP should be monitored and controlled in patients developing coma. In these instances, transient communicating or noncommunicating hydrocephalus may well be the basis for the altered level of consciousness. Other potential causes of raised ICP with altered level of consciousness requires consideration of ICP monitoring such as abnormal cerebral perfusion syndromes, certain toxins, and other infections or infection related processes.[8]

There are several approaches to the monitoring of ICP.[21-23,12] The most frequently used of these is ventriculostomy. All of these procedures may be carried out at the bedside of ICU. Several other approaches have been tried and more are under active investigation which are primarily directed toward making the monitoring less invasive and lessening the risk of infection.

The primary complications of ventriculostomy are intracranial hemorrhage, infection and not measuring what you think you are measuring. Placement of ventriculostomy in the face of high pressure probably has the advantage of tamponade of small vessels in the catheter pathway. As a consequence, placement of the catheter at the peak effect of an osmotic diuretic will tend to lessen this advantage. Also, correction of clotting disorders is a relative necessity depending upon the clinical situation. Significant hemorrhage under these circumstances should be less than 4%. Infection is primarily related to technique and duration of monitoring. For the first 5 to 7 days the risk of ventriculation should be less than 5%. After that period of time, the incidence of infection rises precipitously.[24] In instances of prolonged monitoring, ventriculostomy change should be considered after such a time interval. Problems concerning the reliability of the measurement are less with ventriculostomy than other approaches; however, certain technical considerations increase the likelihood of reliable measurement. Maintaining an appropriate wave form on display gives some indication of the patency of the system. appropriate bridge balance and calibration of the transducer is obvious. Constant ventricular drainage prevents such monitoring; and in circumstances of smaller ventricular system, may cause the collapse of the ventricular system around the catheter. Ventriculostomy has the unique advantages of being able to maintain and control ICP from the same device. Also, the pressures recorded are reliable through out the entire range of ICP measurement. The lack of following at the higher ranges where the measurements become the most significant is the overwhelming disadvantage of other approaches. At pressures above 20 mm Hg, there is serious question as to whether they will be adequately reflected in any current approach than ventriculostomy.[25]

The control of ICP once measurement has been established may be carried out in a stepwise fashion from occasional venting to full scale muscle relaxants, osmotic diuretics, steroids, tight control of $PaCO_2$, barbiturates and occasionally hypothermia. In suspected significantly raised pressure, monitoring should be instituted before intubation if the airway is protected in order to prevent the likely significant rises in pressure associated with most intubation.

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Thoracic Outlet Syndrome: Ten Years Later

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ABSTRACT—Because of its various symptomatology, ranging from numbness of the fingers, trophic changes to severe lancinating pain, the thoracic outlet syndrome (TOS) could be a simple manifestation of compression of the neurovascular bundle or a disabling entity. It has a complex multifaceted etiologies, at least 16 entities have been described[1] and surgeons have devised multiple operations to relieve its manifestations.

The purpose of this paper is to review the different etiologies of the TOS as well as its special manifestations.

The first successful rib was removed by Coote in 1861. In 1956, Peet[2] suggested the term "Thoracic outlet syndrome" to define a group of symptoms resulting from compression of the thoracic neurovascular bundle. Rob[3] in

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1958 changed it to "Thoracic outlet compression syndrome."

The brachial plexus and the axillary artery emerge from the thorax through a triangle formed anteriorly by the scalenus anticus and minimus, posteriorly by the scalenus medius and inferiorly by the first thoracic rib. The axillary vein lies anteriorly to the scalenus anticus muscle. Any change in the relationship between these three anatomic components which tends to narrow the outlet, will cause a variety of symptoms termed as true TOS. Related syndromes may be seen with compression by adjacent structures: cervical ribs, clavicle, pectoralis and subclavius muscles.

Etiology

A. True Thoracic Outlet Syndrome

1. The scalenus anticus muscle originates from the transverse processes of the third, fourth, fifth and six cervical vertebrae and is a lateral flexor and rotator of the cervical spine. Hypertrophy of the muscle is seen on the basis of compensatory hypertrophy or congenitally such as the case of torticollis. In certain individuals, excessive development of this muscle can be noted.

If the insertion of this muscle on the first rib originates more posteriorly than usual, it can narrow the interscapular aperture which normally is around 12 mm.[4] Similar mechanism is encountered with a broad base insertion of the muscle. In many cases, dense fibrous tissues have been found around the base of the muscle itself, further narrowing the aperture.

The scalenus minimus which is more fibrotic than muscular can be abnormally hypertrophied, thus may produce the same compression effect. Finally in the presence of associated cervical rib, the normal scalene muscle can compress the brachial plexus against the cervical rib.

2. Hypertrophy (congenital or due to overactivity) or anterior insertion of the scalenus medius muscle may produce a TOS. They can also cause an entrapment of the dorsal scapular nerve,[6] which originates from C5, passes through the scalenus medius and then turns inferiorly to innervate the rhomboid muscle. The tense nerve moving against a tight muscle may cause pain in the scapular area.

3. The third component involved in this syndrome is the first thoracic rib. It is usually C shaped and mobile, but it can be shortened and take a J shape resulting in an abnormal insertion of the scalene muscle. Incomplete development of the rib has been described.[7] In most of the surgical specimens, the rib is found to be larger than usual. Callus resulting from a rib fracture or an osteochondroma can impinge upon the plexus. Poor posture, sagging of the shoulder girdle during growth, [8] low insertion of the plexus (post fixed plexus), high fixation of the sternum and ribs may produce the same symptomatology.

During reoperation for recurrent TOS, scar formation around C8-T1 nerve roots as well as fibrocalcific bands connecting anterior and posterior rib remnants can be found in the thoracic outlet area.[9]

All these congenital or traumatic anatomical variations tend to narrow the opening and compress the neurovascular bundle. Similar changes can be produced indirectly by adjacent structures.

B. Related Conditions

1. Cervical ribs occur in 0.5 to 1% of the population; they are bilateral in 60-80% of cases,[10] are more frequent on the left side but are symptomatic in only 10% of cases. A cervical rib articulates with the seventh vertebra and varies from a simple exostosis (Gruber type I) to a fully formed rib. If small, the free end of the cervical rib is attached to the first rib by fibrous bands (Gruber type II), and if longer than five centimeters (Gruber type III),[11] it may displace the neurovascular bundle resulting in radicular pain.

2. The costoclavicular syndrome, first reported by Falconer in 1943,[12] is due to compression of the brachial plexus by the medial convexity of the first rib in unusual situations (military salute, hyperextension of the shoulders, etc.). An abnormally enlarged subclavius muscle, a fracture of the clavicle, a callus[13] can produce similar symptoms, as might do the shoulder straps of a heavy pack.[14]

3. In the hyperabduction syndrome,[15] in addition to the costoclavicular syndrome,[16] the tendon of the pectoralis minor was found to compress the plexus. Stallworth[5] demonstrates that the pectoralis major could cause cyanosis of the entire extremity when the arm is held in an adduction position.

4. A long transverse process has a similar action as a cervical rib.

5. Hyperabduction or stretching of the plexus usually causes elongation of the suprascapular nerve[6] at the suprascapular foramen. This results in deep pain in the lateral and posterior aspects of the shoulder.

Symptomatology

Clinical manifestations are usually complex and varied, they are related to compression of the various components of the neurovascular bundle. Nerve symptoms are present in 98% and vascular symptoms in only 5-10% of cases.[18] Compression is minimal in the beginning resulting in subtle symptoms, and occurring only in certain positions; they tend to become progressively permanent later.

1. Impingement of the lower cord of the brachial plexus produces tingling, anesthesia on the medial aspect of the arm, fourth and fifth fingers. Weakness for fine motions of the hand is noted. Motor weakness occurs in 10% of cases. Involvement of the ulnar nerve, which occurs in 90% of cases,[20] forms the basis of the ulnar nerve velocity conduction test designed to help diagnose the syndrome. Involvement of the upper trunk is rare.

The dorsal scapular nerve entrapment results in pain along the medial border of the scapula with diffuse pain radiating down to the arm. Tenderness over the scalene muscle is noted.

Urschell[21] described 44 patients with anginal pain due to TOS. Compression is not the only mechanism in this syndrome. The fact that TOS occurs predominantly in women (70-80%)[22, 23]in the third and fourth decades points to stretching or traction as another mechanism. Irritation, kinking, angulation of the plexus will produce similar symptoms.

2. Compression of the sympathetic fibers results in changes in color, temperature of the skin and later a Raynaud syndrome.[5,20,24]

3. Vascular compression is progressive in most of the cases. Deep aching, ill defined pain is felt from shoulder to the arm. It is accompanied by tingling and numbness. Intermittent claudication of the arm is occasionally seen. Patients tend to drop objects or complain of a weak grip. Blanching of the arm on exertion and a systolic murmur may be noted. Eighty per cent of patients have positive Adson tests, hyperabduction or costoclavicular maneuvers.[23,25]

Further vascular compression will cause spasm of collaterals, intimal injury with secondary thrombosis or atheromatous degeneration.[26] Microemboli to the fingers or retrograde emboli via the innominate artery have been described.[11,27] Turbulence and hemodynamic vibrations due to arterial stenosis may result in post-stenotic dilatation. So far more than 76 cases of post-stenotic aneurysms have been published.[28-30] compression of the subclavian artery occurs either at the thoracic outlet or between the highest rib and the clavicle. Gruber type III cervical ribs are more likely to cause such a compression.[10,11] Arteriography is helpful for detection of these vascular lesions.[8]

4. Venous compression produces a characteristic picture with moderate to large swelling of the arm, reddish blue hue, discoloration, marked venous collateral circulation and an aching feeling of tightness.[31] It is noted predominantly in females, in the right arm[32] favoring the concept of effort thrombosis. Elongation of the neck during growth, descent or sagging of the shoulder, hyperabduction tend to narrow the costoclavicular space causing compression of the vein by the clavicle.[33] Intermittent obstruction of the vein can be seen without thrombosis.[33] The latter may occur with persistent venous compression. It is, however, rare: 1-3% of deep venous thrombosis.[34] Recurrence as well as persistent residual sequellae are attributed to excessive use of the extremities.[35] Pulmonary embolism is rare, even with axillary thrombosis.

Discussion

Clinical diagnosis should be documented and confirmed by a battery of tests including: neurological consultation, x-rays of the neck and chest, angiograms, electromyograms, nerve conduction studies and detailed non-invasive oscillographic recordings of arterial flow during various outlet maneuvers.[5]

The above etiological classification based on anatomical variations, implies a therapeutic approach. In about 90% of cases, patients will improve with aggressive physical therapy and exercises; in the remaining cases, the syndrome may be relieved by various surgical procedures. Partisans of the first rib resection claimed a 96% success with a recurrence rate of 4%.[17] With division of soft tissues alone, Stallworth[5] claimed an improvement of 92.5%. In other cases, combined rib resections, claviculectomy, and/or soft tissue division may be required.

After an explosive interest in this entity in the early seventies, ten years later, the interest seems to have faded away. Surgeons probably have learned to recognize "true symptomatic TOS," which required a surgical approach from the "pseudo TOS" manifested by vague symptomatology. Nothing is more depressing than to bring a 30-year-old female with some neck pain, numbness in the right hand, and a past history of minor car accident, to surgery and realize that the pain is still there or may be worse post-operatively. What remains true are the clinical presentation, the anatomy of the syndrome, but aggressive surgical therapy is not warranted in all patients.

The lesson to learn from this entity, as well as from the so called "median arcuate syndrome" (compression of the celiac axis by the median arcuate ligament manifested by epigastric pain) is that pain is something very suggestive, and is very difficult to treat, especially by a "pure" surgical approach.

Conclusion

Clinical manifestations of the TOS are multiple and varied. Some of them are disabling. Mechanical compression of the thoracic neurovascular bundle is thought to be one of the causes. But anatomical etiologies are multiple and have been reviewed in this paper. Aggressive palliative, non-surgical treatment is advised for most patients. In selected cases, surgery including rib resections or soft tissue divisions, may be indicated.

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Hospice Inpatient Care: Characteristics of an Institution and its Patients

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ABSTRACT—A brief description of the medical aspects of inpatient hospice care in a free-standing facility is presented. Admission criteria and categories of admission are reviewed. The charts of 200 discharged patients were abstracted. Data concerning their demographics, diagnoses, signs, symptoms, and other conditions, and their medical care are given. A brief discussion of the role of the physician in hospice care is included.

Introduction

Specialized care for the terminally ill, a concept that has come to be known as hospice, is relatively new in American medicine. One of the first free-standing hospice facilities in this country began operations in Connecticut in 1980, thus placing the state in the forefront of the movement. One of the stated objectives of this institution is to promote and contribute to the medical knowledge of physicians, nurses, and para-medical personnel. To this end, data concerning the characteristics and therapy of two hundred inpatients are presented. The role of and need for physicians in the hospice setting are examined in some detail to support the belief that physicians are a necessary and integral part of the health care team that provides hospice care.

The Hospice

The institution accepts patients who fulfill certain criteria for three general categories of admission. The most important of these categories is terminal care, which is best characterized as being palliative and supportive and which lasts until the patient expires. The amount of sup-

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portive care provided is minimal and is generally confined to oral feeding for as long as possible, the treatment of distressing symptoms by simple means, and other measures to improve the general physical comfort of the patient. Intravenous fluids, medications or blood products, respirators, cardio-pulmonary resuscitation and the like are not considered appropriate except in unusual circumstances. Specific anti-neoplastic therapy is withheld unless it is thought to be necessary to relieve symptoms. Treatment of other disease states, especially intercurrent infections, is often stopped or never begun. Patients are allowed to succumb to their disease as comfortably as possible; measures that simply prolong life are avoided.

Hospice may also provide two other types of care: symptom control and respite care. Symptom control takes the form of an inpatient admission for whatever period of time it may take to control a specific symptom. The means utilized to this end are of such a nature that they may be continued at home or in the extended care facility from which the patient was admitted. While parenteral medications and other treatments by skilled health care professionals may be used to relieve distress, methods that maintain relief and can be easily used at home must eventually be developed. The category of respite care consists of a brief, usually two week inpatient admission for individuals who are being cared for at home but whose families need a break from providing that care.

Because the type of care given depends to some extent on the expected outcome of the hospitalization, the reason for the admission (terminal care, symptom control, respite care) must be made clear at the time of hospitalization. A person admitted for the control of severe pain, for example, will be maintained on all of the medications he or she is receiving, including vitamins, anti-cancer drugs, and so on. That same individual, admitted for terminal care, would be placed only on those medications necessary to keep him or her comfortable. Again, if the patient were admitted for respite care, blood transfusions and other life sustaining measures might be employed which would not come into play if the stated purpose of the hospitalization were for terminal care.

The criteria used to determine a patient's eligibility for admission are several. It is necessary for the patient to have been diagnosed as having an incurable disease with a limited prognosis of weeks or months, not expected to be more than six months. The patient generally has uncontrolled symptoms, home care is not appropriate, and he or she has a referring physician. Connecticut residents have preferred status but out-of-state individuals with friends or relatives here are accepted when room permits. The initial referral need not be made by the patient's physician but the latter is always contacted prior to admission. Patients are rarely admitted against the expressed wishes of their physician of record. During the hospitalization the referring physician may visit the patient and be consulted by a staff physician but the latter assume responsibility for all of the patient's medical care.

Study Design

Hospital charts were abstracted following the patient's death or discharge. From each chart data was collected pertaining to: a. age; b. sex; c. date of admission; d. consults obtained from members of the pastoral, social work, respiratory therapy or arts department and/or staff psychiatrists; e. consults from outside physical therapists, podiatrists, and/or dentists; f. the presence of certain signs, symptoms, or other situations and; g. the use of drugs and oxygen.

The parts of each chart that were examined were: a. the header record (which contains all information obtained about the patient, usually by telephone, prior to admission); b. the staff physician's admission history and physical examination; c. patient assessment sheets (these are standard forms completed by the nursing staff during the first few days of hospitalization); d. physician order sheets; e. Cardex sheets; f. daily progress notes; g. medical records from other institutions and physicians and; h. the death certificate.

In examining the data occasional conflicts in information, such as different diagnoses on the admission history and the header record, cropped up. These conflicts were resolved by the author's judgment of what, in each individual case, was the correct information. The symptoms, signs, and other conditions referred to by the tables in this paper are those that are used to determine patient status. This is in turn used by Utilization Review to determine allowed length of stay.

Results

Two hundred charts, representing 76% of the deaths or discharges over a five-month period, were reviewed. There were 102 males and 98 females in this sample with ages ranging from 17 to 94 years. The mean and median ages were 69.8 and 70.0 respectively. Length of stay ranged from 1 to 111 days, with a mean stay of 17.7 days. The primary reason for admission in 161 patients was terminal care, 21 were admitted for symptom control, 10 were admitted for respite care, 6 were admitted for symptom control plus respite care, one was admitted for "rehabilitation," and there was no discernible reason for the admission of one patient. When the reason for admission was given as terminal care plus either respite or symptom control only terminal care was recorded; it being assumed that respite care and symptom control are part of that care.

Of the 200 patients represented by these charts, 180 died in the hospice. Of the 20 patients discharged, 8 were originally admitted for terminal care and the others for respite care and/or symptom control. Twelve of the 20 discharged patients returned home, four were sent to an extended care facility, and four to an acute care hospital for further evaluation or therapy.

Admission Diagnosis

The admission diagnoses are listed in Table 1. The disease process recorded is the one responsible for the

Table 1
ADMISSION DIAGNOSES

	MALES	FEMALES
Single Malignancy of:		
Lung	21	18
Breast	0	17
Prostate	10	
Uterus		7
Ovary		5
Head/Neck	5	4
Esophagus	6	0
Stomach	0	3
Colo-Rectal	16	12
Pancreas	5	4
Liver	2	2
Urinary Bladder	6	1
CNS	11	5
Kidney	2	0
Melanoma	3	0
Lymphoma	1	2
Chondrosarcoma	1	0
Cutaneous: Vulva		2
Mesothelioma	1	0
Primary Site Unknown	3	8
Multiple Malignancies of:		
Pancreas, Thyroid	0	1
Lung, Kidney	1	0
Lung, Bladder	1	0
Colon, Breast	0	2
Colon, Breast, Lung	0	1
Colon, Head/Neck	1	0
Colon, Melanoma	0	1
Pancreas, Breast	0	1
Non-Malignant Diseases		
Amyotrophic Lateral Sclerosis	1	0
Multiple Myeloma	2	1
Biliary Obstruction	0	1
Stroke	1	1
Congestive Heart Failure	0	1

hospice admission but is not necessarily the cause of death on the death certificate. One hundred and eighty-three persons had a single malignant disease process, nine had multiple malignancies, and eight had other types of illnesses. The author attempted to place the malignancies in the same categories, by site, as the American Cancer Society uses but difficulties were encountered when trying to distinguish between the different types of buccal cavity and pharynx cancers and those of the digestive organs. The author chose instead the categories "head and neck," 'esophagus," and "stomach." Two of the nine patients in the first of these categories were men described as having cancer of the pharynx and esophagus and three had cancer of the larynx and pharynx. Two of the six patients with cancer of the esophagus had a malignancy of the gastroesophageal junction.

Eleven patients had a metastatic malignancy of unknown origin. One of these was a female with a past history of endometrial carcinoma and one was a woman who had had a breast removed. The single male patient with mesothelioma had involvement of the thoracic and abdominal cavities but the records did not indicate the initial site. One of the men with prostatic carcinoma also had Kaposi's sarcoma of the left foot but the latter disease did not contribute to his terminal state and his case was therefore not counted as a multiple malignancy.

Consultations

Table 2 shows the consults performed by staff members (arts, social work, pastoral, respiratory therapy departments and psychiatry) or by outside consultants (dentistry, podiatry, and physical therapy). Arts and pastoral personnel see patients without specific requests although special consults can be done within these departments.

Table 2
CONSULTATIONS

Arts Department	78
Dentist	7
Pastoral Department	144
Physical Therapy	13*
Podiatrist	4
Psychiatrist	6
Respiratory Therapy	22
Social Work Department	51

*three of these patients were evaluated for, and eventually treated with transcutaneous electrical nerve stimulation (TENS).

Table 3
SIGNS, SYMPTOMS, AND OTHER CONDITIONS

	# of patients with	*% of patients with written M.D. orders*
General		
pain	185	98
anorexia	21	5
insomnia	33	100
weakness	109	unable to determine
dehydration	3	33
fear	28	unable to determine
anger	18	unable to determine
fever	49	24
family stress	17	53
Gastrointestinal		
nausea/vomitting	81	99
diarrhea	26	58
constipation	144	12
fecal incontinence	109	unable to determine
intestinal obstruction	12	100
dysphagia	42	26
colostomy	17	unable to determine
gastrostomy	6	100
nasogastric tube	2	100
feeding jejunostomy	2	100
Mucocutaneous		
decubitus ulcer	75	89
open wound/tumor	33	unable to determine
oral thrush	51	98
Neuropsychiatric		
seizures	22	100
depression	51	35
confusion	108	78
agitation	87	96
anxiety	55	92
hallucinations	15	93
Respiratory		
shortness of breath	32	75
dyspnea	23	70
cough	79	50
Urinary Tract		
incontinence	109	39
Foley catheter	65	100
texas catheter	22	100

All other consultations are performed only at the specific request of a staff physician. Members of the dietary staff often perform consultations but they are not recorded in the chart.

Signs, Symptoms, and Physical Condition

Table 3 tabulates the signs, symptoms, and physical condition of the patients in the sample along with the percentage of patients within each category who were treated, when applicable, with medication ordered by a physician. One hundred and eighty-five patients were deemed to have pain and in most cases this problem was specifically addressed in the chart by the medical or nursing staff. For a few patients, however, the presence of this symptom was deduced by the fact that the patient was on regular doses of a narcotic. The presence of nausea and/or vomiting, while usually discussed in the chart, was at times inferred by the fact that the patient was on regular doses of prochlorperazine or metoclopramide. These two drugs are rarely used at Hospice for other symptoms. Other medications such as scopolamine and hydroxyzine have common other uses and were thus not used to infer the presence of nausea-vomiting. All other signs, symptoms, and physical conditions, were taken directly from the mention of such in the chart.

Medications and Oxygen

Table 4 shows the use of medications and oxygen. The latter is ordered on the doctor's order sheet, and its use documented in daily progress notes. Standing orders allow the nursing staff to dispense certain drugs without a physician's order for mild discomfort or pain, fever causing patient discomfort, periodic complaint of gastric distress, complaint of dry eyes, excessively dry skin without presenting dermatologic problems, complaints of burning, itching, or pain with external hemorroids, and routine bowel care. The drugs so dispensed are aspirin 650 mg. p.o. or p.r., acetominophen 650 mg. p.o. or p.r., Lubriderm Lotion, Eucerin Cream, Anusol Ointment, Tucks Pads, Pericolace capsules or liquid 100 mg. one to four times daily, Colace capsules or liquid 100 mg. one to four times daily, milk of magnesia with cascara suspension 30 cc at h.s., Dulcolax 10 mg. suppository, Fleets Brand Enema, soap suds enema, Maalox-Plus Suspension 15-30 cc, and artificial tears. Artificial saliva was used as needed without any order. The medication sheets have space for the charting of the bowel medications listed above. Other standing order medications are to be charted on the medication sheet by the nurse dispensing them. All other medications were ordered on the medication sheets, and their use is also documented there.

Table 4
MEDICATIONS AND OXYGEN

	number of patients receiving
Narcotics	
morphine	149
oxycodone	48
hydromorphone	8
codeine	5
levorphanol	10
methadone	2
meperidine	8
Non-Steroidal Anti-Inflammatory Drugs	
aspirin [1]	73
acetominophen [1]	47
ibuprofen	8
naproxen	14
zomepirac	2
indomethacin	6
Miscellaneous Drugs used for Analgesics	
carbamazepine [2]	9
levodopa [2]	3
diphenhydramine + Maalox [3]	5
Gastrointestinal Drugs	
prochlorperazine	65
scopolamine	19
metoclopramide	2
cimetidine	16
bisacodyl tablets	4
citrate of magnesia	3
psyllium	3
senakot	3
docusate sodium with casanthranol [1]	84
bisacodyl suppository [1]	71
milk of magnesia	70
fleet brand enema [1]	27
soap suds enema [1]	6
docusate sodium [1]	14
Anti-Bacterial Anti-Biotics	
systemic	34
topical and opthalmic	29
Anti-Fungal Anti-Biotics	
systemic	57
topical	21
Anti-Viral Anti-Biotics	1
Anti-Cancer Drugs	
DES	1
Tamoxifen	8
Psychotropic Drugs	
oxazepam	88
diazepam	60
haloperidol	37
chlorpromazin	28
chloral hydrate	30
anti-depressants	18
stimulants	2
Respiratory Drugs	
guaifenesin	28
isoetharine	11
theophylline	21
miscellaneous	7
Others	
anti-convulsants	30
anti-hypertensives	42
anti-histamines	17
steroids: systemic	71
topical	16
cardiac drugs	47
thyroid drugs	6
op-site	35
anti-diabetic agents	8
miscellaneous	28
oxygen	42

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[1] standing order medications
[2] used for pain of metastases to bone
[3] topically for mucosal pain

Discussion

The foregoing description of the categories of admission and admission criteria, as well as the summary of 200 patients and the care they received, will hopefully help to broaden the knowledge that Connecticut physicians have of hospice care and the types of inpatient services available. One anomaly that deserves further thought and discussion is the paucity of non-cancer patients in the sample used by this study. Of these 200 patients admitted over a five month period, only eight were not afflicted with cancer. Since cancer is not the leading cause of death in the United States, the reason for this low number is not self-evident. The admission requirement for a prognosis of six months or less, however, may be at least partly responsible. To make such a prognosis for a person suffering from degenerative nervous system disease, heart disease, or stroke, is considerably more difficult than it is to make for the cancer patient. The eight non-cancer patients in this study had a mean length of stay of 12.2 days. Only one patient was transferred to an acute care facility for further evaluation after three inpatient days at hospice. One patient was admitted in coma, living for a week. The other six had a length of stay similar to the entire patient population (13.3 days), were conscious on admission, and died in the hospice. This is testimony to the clinical acumen of their referring physicians. It is also likely that many Connecticut physicians, as well as lay people, associate hospice specifically with cancer and not with other chronic diseases as they near their end.

Since the role of the physician is usually associated with the restoration of health and the prolongation of life, his or her position within hospice is occasionally questioned. It is clear, however, that a large majority of the patients reviewed in this study had symptoms, signs, and physical and other conditions that required the attention of a physician. The most obvious need is in the treatment of pain. Fifty-one patients, over 25% of the patients in the sample, were treated with two different narcotic analgesics and eight received three different narcotics. Carbamazepine and levodopa, medications that are not simple analgesics or anti-inflammatory drugs, were also used for analgesia. Systemic steroids and anti-neoplastic medications were used by 71 and 9 patients respectively, in many cases for treatment of pain. Sedatives and tranquilizers, especially phenothiazines, were used to potentiate the action of narcotics, as were stimulants and antidepressants, and transcutaneous electrical nerve stimulation was tried and found to be helpful in three cases.

In a hospice setting it is particularly important that pain and other symptoms be treated adequately, as successful symptom control is a basic goal of hospice care. Pain control cannot be approached in a "cookbook" manner but must be accomplished based on knowledge of the pathophysiology of the particular pain being treated. In hospice care the source of pain is identified as accurately as possible without resorting to more than a history and physical examination. Knowledge of pathology, physiology, anatomy, and pharmacology are therefore all necessary in order to devise a plan of pain relief for each individual. In the majority of patients with troublesome symptoms such as nausea, vomiting, or insomnia, treatment was with measures ordered by a physician. Even the treatment of constipation, thought usually to be the responsibility of the nursing staff, was specifically addressed by a physician in a number of cases.

The voluminous nature of charts in the Hospice inevitably makes for the under-reporting of some data. The chart reviewer had difficulty extracting all pertinent information because of the charting system used at Hospice. Problem oriented charting is not used and, unlike most hospitals, in Hospice progress notes are not differentiated by discipline. All disciplines therefore chart in the same "daily progress notes" and charting by physicians is minimal and difficult to find. Because of the latter, it was frequently impossible to relate a particular drug, treatment, or consult, to a particular symptom or condition.

The condition of the raw data itself produces similar errors. A common source of under-reporting is that standing order medications are at times not charted by the nurse dispensing them in the proper place on the medication sheets. Information concerning their use was also often omitted from daily progress notes and was found only in the informal reports that nurses use at a shift change. These do not become part of the permanent record.

Treatment of several specific problems was frequently done by the nursing staff either via verbal doctor's orders or with substances that should have required a written order but were usually used without formal orders. For example, treatment of decubitus ulcers often included the use of Op-Site, as well as hydrogen peroxide, benzoin, zinc oxide paste and ointment, oral antacids, or topical lidocaine. These substances may or may not have been ordered in writing. Minor skin irritations, as from incontinence or around stomata, were often treated with the same medications without the benefit of a written order though it should be noted that in most cases such therapy was discussed with the staff doctor. Counseling for neuropsychiatric symptoms and family stress was at times performed by the medical staff without orders for such counseling being written. In the case of anorexia the most common therapy is dietary manipulation including the use of spirits. This, again, is done without written but with verbal doctor's orders. These various shortcomings of the chart-review method used in this study do not, in the author's opinion, affect the validity of the general picture drawn of hospice in this paper.

In closing this paper the author would like to add a personal note, based on her own experience in treating hospice patients, to the physicians reading this paper. Hospice care is concerned with the relief of distressing symptoms and the daily comfort of the patient whereas "curative" medicine may be said to have as its primary goal the restoration of health and the prolongation of life. This is not to say, however, that the two are incompatible and there is every reason to believe that the best practitioners of conventional medicine will also be the best practitioners of hospice medicine. Though this paper deals with inpatients at a specialized hospice facility, it should be clear that the same care can be given at home, in conventional hospitals, in extended care facilities, and in other institutions. Hospice care at the end of life should be an extension of the medical care that an individual has received throughout his life, in the context of his home, family, and friends, and provided by his family doctor or any other physician with whom the individual has a relationship. Any physician who wants to provide this very important service for his patients can easily do so. The physician may have to educate himself better in symptom treatment, may have to give more of himself and his time, and may have to avail himself of the consultative services of experienced hospice physicians to address particularly difficult problems; but any general practitioner or family doctor, internist or surgeon, can give his dying patient all of the medical care he needs.

Oculoplethysmography (GEE): Value and Limitations

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ABSTRACT—This study is a retrospective analysis of 164 patients who underwent both oculoplethysmography (OPG) and carotid angiography, undertaken to evaluate the sensitivity, specificity, and accuracy of the OPG test. A second goal of the study was to determine the most accurate criteria for a hemodynamic carotid stenosis. Analysis of the data with a Receiver Operating Characteristics Curve revealed that a combination of two OPG criteria for a stenosis offer the most accurate OPG results: 1) a difference between the right and left ophthalmic artery systolic pressures of $\geq$ 5 mm. Hg. and/or 2) an ophthalmic artery systolic pressure to brachial artery systolic pressure ratio (OSP/BSP) of $\leq$ 62%. The second of these criteria represents a departure from those previously reported by others. Using the above criteria the OPG test was found to be very sensitive (97%) to severe stenotic disease (80 to 100% cross sectional stenosis by carotid angiography). The sensitivity to less severe lesions (50 to 79% diameter stenosis) was 67%.

Oculoplethysmography has been the principle noninvasive screening technique used in the evaluation of carotid artery stenosis in the Non-invasive Vascular Laboratory of Hartford Hospital. This study is a retrospective analysis of 164 patients who underwent both oculoplethysmography (OPG) and carotid angiography. The study was undertaken to determine the best criteria for an abnormal OPG test and then to apply these criteria to determine the sensitivity, specificity and accuracy of OPG.

Patients and Methods

The OPG technique used was that previously described by Gee and co-workers[1, 2] and involves the use of 14 mm. bilateral air-filled eye cups applied to the sclerae, attached to a calibrated vacuum unit (300 mm. Hg. or 500 mm. Hg, depending upon blood pressure), which measures the systolic pressure of each ophthalmic artery. This is the first branch of the internal carotid artery and a hemodynamically significant stenosis of the carotid artery causes a decrease in the ophthalmic artery pressure. By comparing the ophthalmosystolic pressure (OSP) of the two eyes or comparing the OSP of each eye with the brachial systolic pressure (BSP) and applying the appropriate OPG criteria, it is possible to detect significant

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carotid stenosis.

In order to maximize the accuracy of the OPG test, we systematically evaluated different OPG criteria by the Receiver Operating Characteristics (ROC) curve of McNeil and associates.[3] Using this technique we found that we could maximize the accuracy of the OPG test by using two criteria for hemodynamically significant stenosis: 1) a difference between the OSP of each eye ≥ 5 mm. Hg. (with the lower pressure representing the stenotic side) and/or 2) an OSP which is ≤62% of the brachial systolic pressure (BSP). This OSP/BSP ratio of ≤ 62% is less than the ratio of ≤ 66% which we, as well as other authors [2,4] have previously used. The two above criteria are felt to be complimentary, with the first being more applicable to unilateral disease and the second more applicable to bilateral disease.

From June 1, 1980 to June 1, 1982, a two year period, there were 1,906 OPG studies carried out in our Noninvasive Vascular Laboratory at Hartford Hospital. 164 of these patients underwent carotid angiography at the discretion of the referring physician.

All carotid angiography was done by two neuroradiologists at Hartford Hospital and consisted of selective carotid arteriorgrams taken in both the lateral and anteroposterior projections. All stenotic lesions found by angiography were expressed as percent diameter stenosis of the distal internal carotid artery. Lesions ≥ 50% stenosis by diameter (75% stenosis by cross section area) were considered hemodynamically significant and were termed positive for purposes of comparison with OPG results. Sensitivity, specificity and accuracy of the OPG technique were determined by comparing the OPG results with the angiography results, with analysis by artery and by patient. Results also were correlated with various grades of stenosis.

Results

An analysis of the false positive and false negative OPG results in our study revealed that any change in the ≥ 5 mm. OPG criterion described above, in order to improve sensitivity, would be offset by a decrease in specificity and vice versa. The second OPG criterion, OSP/BSP ratio was systematically varied and coupled with the ≥ 5 mm. rule in order to produce the most accurate and informative test. This evaluation is expressed in Figure 1, in the form of a Receiver Operating Characteristics (ROC) curve. On this curve the Y axis, the true positive ratio (TP), is a measure of sensitivity, while the X axis, the false positive ratio (FP), is inversely related to specificity. Each point on the graph represents the resultant TP and FP ratios when a given value for the OSP/BSP criterion is coupled with the ≥ 5 mm. criterion. This curve allows one to systematically evaluate the dynamic relationship to one another as the criteria of the test for abnormality is changed. Examination of this curve shows an OSP/BSP value of 62% to be the most accurate point. As the OSP/BSP value is reduced toward 62% from 74%, losses in sensitivity are offset by larger gains in specificity. As the OSP/BSP criteria are decreased below 62% the loss in sensitivity of the test becomes greater than the gain in specificity. Thus the most accurate OPG criteria for evaluation of hemodynamically significant stenosis are 1) a difference of ≥ 5 mm. between the two ophthalmosystolic pressures and/or 2) an OSP/BSP ratio which is ≤ 62%.

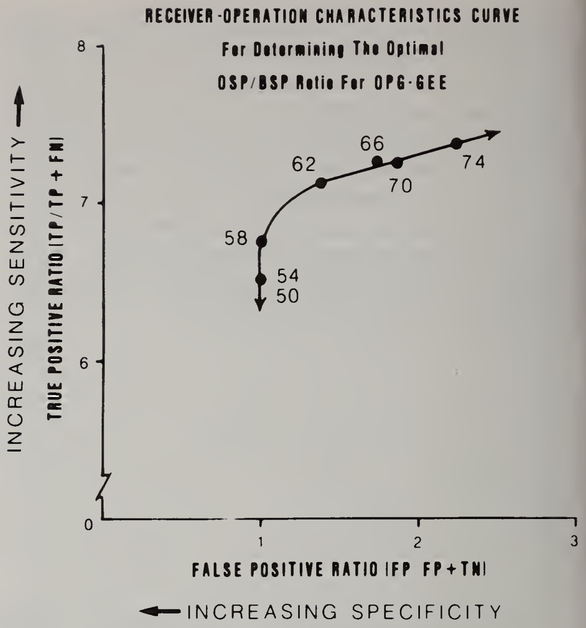

Figure 1
A Receiver Operating Characteristics Curve: The True Positive ratio is a measure of sensitivity. The False Positive ratio is inversely related to specificity. Each point on the graph represents the resultant TP and FP ratios when a given value for the OSP/BSP criteria are coupled with the ≥ 5 mm. criteria described in the text. An OSP/BSP of 62% marks the most informative point of the curve.

As shown in Table 1, when the above criteria are applied to the 329 arteries studies by both OPG and carotid angiography there was a sensitivity (i.e. the ability to identify true positives: Sensitivity = TP/TP + FN) of 71% in detecting carotid diameter stenosis of ≥ 50%. At the same time the specificity (i.e. the ability to identify true negatives: Specificity = TN/TN + FP) was 85%. The accuracy of the OPG in the evaluation of 329 arteries was 78% (Accuracy = TP/TN/All).

Table 1
RESULTS OF OPG BY ARTERY

Results of OPG	*Number of Arteries*	*OPG compared to Arteriogram*
True positive (TP)	109	Sensitivity = 71%
True negative (TN)	148	Specificity = 85%
False positive (FP)	27	Overall Accuracy = 78%
False negative (FN)	45	

Table 2 shows the sensitivity of OPG in detecting various levels of stenosis. The OPG was quite sensitive to high grade stenosis with an 84% sensitivity in the detection of lesions which were 80 to 100% occluded. Within this group, 93% of the totally occluded arteries were

Table 2
DETECTION OF VARIOUS DEGREES OF STENOSIS BY ARTERY

Percent Diameter Stenosis	*Total Number of Arteries*	*True Positives*	*False Negatives*	*SENSITIVITY*
50-79%	50	22	28	44%
80-100%	105	88	17	84%
100%	30	28	2	93%

detected. The OPG was much less sensitive in detecting lower grade lesions, showing a 44% sensitivity in the detection of arteries which were 50 to 79% stenotic by angiography.

Table 3 shows the results of OPG when applied to each patient rather than each artery. The sensitivity of the test improved to 89% as compared to 71% in analysis by artery. The specificity of the test dropped to 58%, as compared to 85% in the analysis by artery. The overall accuracy was 79% when the OPG was applied to each patient. The lower specificity is predictable since each patient has two arteries and, therefore, two chances of becoming a "false positive"in analysis by patient.

Table 3
RESULTS OF OPG BY PATIENT

Results of OPG	*Number of Patients*	*OPG compared to Arteriogram*
True positive (TP)	102	Sensitivity = 89%
True negative (TN)	29	Specificity = 58%
False positive (FP)	21	Overall Accuracy = 75%
False negative (FN)	12	

Table 4 shows the ability of OPG to detect various grades of stenosis in analysis by patient rather than by artery. In this analysis each patient is categorized by his most stenotic carotid artery. As shown in Table 4, of those patients having one or both arteries 80 to 100% occluded, 97% were detected by OPG. All 20 of the patients with a total occlusion were detected in analysis by patient. Only 67% of those with 50 to 79% stenosis were correctly identified.

Comment

Thirty of the 45 false negatives in the analysis by artery were in patients who had bilateral carotid disease, but were identified by OPG as having unilateral disease. OPG is a more sensitive screening technique when it is applied to the patient as a whole rather than to each individual artery. Moreover, the goal of the non-invasive study of the carotid arterial system is to identify the patient with disease who needs arteriography and possibly reconstructive surgery.

We have found OPG to be very sensitive (97%) in detecting patients who have 80 to 100% transverse diameter stenotic lesions in one or both carotid arteries. High sensitivity is the most important feature of any screening test which evaluates patient for a disease with potentially serious consequences if undetected. It was disappointing that OPG was less sensitive (67%) in detecting patients who had 50 to 79% transverse diameter stenosis. Decreased sensitivity to lower grade lesions is a problem previously identified by others with the OPG-Gee test.[4] Since the OPG test is a physiological test dependent on hemodynamic changes, lesions of less hemodynamic significance are expected to be less well detected. Variation in collateral circulation and integrity of the circle of Willis are undoubtedly responsible for some false negative results. Also the "Gold Standard"of carotid arteriography has recently been questioned.[9] It has been shown there is excellent agreement among observers in regard to high grade carotid stenoses, but very poor agreement in observers with stenoses less than 80%.

The specificity of 58% when the OPG was applied to individual patients was troublesome. To explain this problem we retrospectively reviewed the 21 false positive studies in our series. Four of these patients had a BSP ≥ 200 mm. Hg. Although our numbers are small (4 patients) we observed a 100% incidence of false positives in normal patients who had BSP ≥ 200 mm. Hg. All of these patients were falsely detected as abnormal based on an OSP/BSP of ≤ 62%. It is possible that a different higher threshold value of abnormality should be applied to those hypertensive patients with BSP ≥ 200 mm. Hg. It has been suggested that a different eye cup application be used in hypertensive patients.[10] One of the 21 false positive studies could be explained by an isolated ophthalmic artery lesion. Another false positive study was attributable to an arteriovenous shunt which was felt to lower the ipsilateral ophthalmic artery pressure. A third false positive study may have been attributable to a tortuous internal carotid artery seen on angiography, although there was no definitive stenotic lesion greater than 50%. Seven of the 21 false positive studies were retrospectively read as negative. Finally the remaining 7 false positive studies could not be explained. One would conjecture that there was an unrecognized ophthalmic

Table 4
DETECTION OF VARIOUS DEGREES OF STENOSIS BY PATIENT

Percent Diameter Stenosis	*Total Number of Patients*	*True Positive*	*False Negative*	*SENSITIVITY*
50-79%	27	18	9	67%
80-100%	89	86	3	97%
100%	29	29		100%

artery lesion or that there was some abnormality of the ocular globe itself. Although this review of false positive studies was retrospective, it is felt that specificity can be improved by a more precise interpretation of ophthalmic artery pressure. There is room for observer disagreement in interpreting which ocular pulse should be read as the first significant pulse.

The overall accuracy of 79% which was achieved was well within the range of accuracy previously reported by others. Accuracies have been reported from 31% (5) to 97% (6). A number of explanations could be offered to explain the wide variety of reported accuracies. First, different laboratories consider different degrees of stenosis to represent hemodynamically significant disease. Arbitrarily, a 50% diameter stenosis (75% cross sectional area) was chosen as a hemodynamically significant lesion. Others have contended that a 75% transverse diameter stenosis is required to reduce flow or pressure across a carotid stenosis.[7] The use of this criterion would undoubtedly improve the sensitivity of the OPG-Gee test.

A second important factor, as argued by O'Donnell,[8] in comparing accuracies reported by different laboratories is that accuracy (unlike sensitivity and specificity) is a parameter which is affected by the prevalence of the disease in the population studied. Since different laboratories may be studying populations with a different prevalence of carotid disease, the reported accuracies may vary.

A third possible factor causing variation in the accuracy reported by different laboratories with OPG-Gee is that different groups use different criteria for interpreting a test as abnormal. In this study we used the Receiver Operating Characteristics Curve to determine the most accurate criteria. With this curve we arrived at an OSP/BSP ratio of $\leq 62\%$ as representing the threshold value for abnormality. This was the most accurate indicator of abnormality in our laboratory.

We have found oculoplethysmography to be an acceptable screening test for carotid disease. It has proven very sensitive to patients with severe carotid stenosis, and somewhat less sensitive for patients with less severe stenosis. There was an undesirably high incidence of false positives, but analysis indicated that this can be improved. The Receiver Operating Characteristics Curve proved to be a useful technique for maximizing the accuracy of the OPG test in this laboratory.

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Important Advances in Clinical Medicine

Epitomes of Progress—Obstetrics and Gynecology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in obstetrics and gynecology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy parctitioners, students, research workers or scholars to stay abreast of these items of progress in obstetrics and gynecology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Obstetrics and Gynecology of the California Medical Association and the summaries were prepared under its direction.

Exchange Transfusion in Pregnant Women With Sickle Cell Disease

The first published article suggesting that exchange transfusion might be used for prevention as well as treatment of sickle cell disease complicated by pregnancy appeared in 1963. This rather aggressive approach attempted to address the 10% maternal death rates being reported at that time and pregnancy wastage (abortion and perinatal death) that varied from 40% to 60%. Only in the past few years, however has this modality achieved rather widespread use, which has been reinforced by recent reports suggesting an improvement in both maternal and fetal outcome. Prophylactic partial exchange transfusion (PPET) reduces the concentration of hemoglobin S by replacing it with hemoglobin A, which offers better tissue perfusion and oxygenation. Other possible advantages of this therapeutic approach include suppressed hemoglobin S erythropoiesis, an increased sense of well-being, reduced infections, reduced crises (both frequency and intensity) and improved perinatal outcome.

Despite these potentially positive factors, there are disadvantages to this approach—both real and theoretical; thus not all physicians are in accord with the recommendation for this procedure in pregnant women who have sickle cell disease. With prophylactic partial exchange transfusion, large numbers of blood cells are transfused and isosensitization remains a serious threat to patients. The other possible disadvantages include hepatitis, anaphylaxis, volume overload, hemochromatosis, premature labor and psychological dependence.

Risks are minimized by the use of washed, buffy coat-poor erythrocytes—which decreases the number of leukocytes, a very frequent cause of transfusion reactions. The risk of hepatitis is also lessened by using washed cells. Further, consanguineous donors who have no sickled hemoglobin should be used to reduce the chance of atypical antibody formation. The potential problem of iron overload seems more theoretic than real. With PPET, iron is also removed, albeit a smaller amount than that which is replaced. Women in addition are relatively protected by periodic blood loss associated with menstruation, iron loss to the fetus during pregnancy and the blood loss that attends parturition.

Most physicians thus far have used a manual method to conduct PPET, which, after hydration, involves the removal by phlebotomy of whole blood and the rather awkward replacement of packed cells containing hemoglobin A. The possibility of volume overload, although an infrequent occurrence, should not be overlooked. Moreover, with this manual method there is a permanent loss of a patient's endogenously produced plasma, platelets and leukocytes. More recently a transfusion technique known as automated erythrocytapheresis has been used. With this technique, a continuous flow system withdraws a measured volume of a patient's blood and selectively removes from it by differential centrifugation the hemoglobin S-containing erythrocytes. The patient's remaining plasma, platelets and leukocytes are returned to her circulation, along with an aliquot of hemoglobin A-containing donor erythrocytes.

As stated earlier, the risk-benefit ratio of this therapeutic approach is unclear and because of this a

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consenus development conference on this subject was convened in 1979 by the National Institutes of Health. I hope that the issues raised in this article can be answered through a randomized multicenter collaborative study such as that suggested by the consensus development conferees.

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The G Suit in the Management of Intra-abdominal Hemorrhage

One of the most effective therapeutic procedures available to an obstetrician-gynecologist for the control of intractable abdominal hemorrhage is the gravity (G) suit. The G suit is also known as the MAST suit (military antishock trousers) and the antishock suit. It was used extensively in the Vietnam War, allowing transport time to base hospitals of severe trauma casualties and thus saving many lives. It is also used extensively throughout the United States by paramedics when transporting a patient in shock to a hospital. The G suit consists of three inflatable chambers, one for each leg and one for the abdomen. Inflation of these chambers to a pressure of 10 to 20 mm of mercury creates a circumferential compression of the vessels in the abdomen and legs, which has two effects. First, it causes a shunting of blood from the legs and abdomen to the vital structures of the head and chest; it has been estimated that an autotransfusion of as much as 750 to 1,000 ml of blood can occur depending on a patient's size and blood volume. Second, the use of the G suit has a hemostatic effect by reducing the radius and the tension of vessel walls, allowing clot formation.

The G suit's application in obstetrics and gynecology is primarily in the treatment of hemorrhagic shock. There are many clinical situations in which its use is most appropriate. One of the most dramatic is in treating shock in a patient with a ruptured ectopic pregnancy. Patients in shock respond to application of the G suit with a rise in their blood pressure and a slowed pulse rate, thus allowing time to restore blood volume and to transfer the patient to the surgery for a definitive procedure.

Postoperative bleeding due to oozing and raw vascular beds that cannot be controlled by good surgical technique and packing can be very effectively controlled by using a G suit. Some examples would be for oozing after hysterectomy in patients with extensive adhesions due to chronic pelvic inflammatory disease or endometriosis; after cesarean section for placenta previa, especially when implantation has occurred at the site of a previous scar; uncontrolled venous bleeding in a space of Retzius after suprapubic bladder neck suspensions, and after cesarean hysterectomy oozing due to the increased vascularity. By using the G suit in a prophylactic manner for 24 to 36 hours, the frequency of second operations and hematomas can be reduced.

Postpartum hemorrhage due to uterine atony may be effectively controlled by using the G suit. Patients aborting and those passing a hydatidiform mole who are hemorrhaging excessively and in shock respond to application of a G suit until definitive therapy can be implemented. Patients in septic shock without blood loss can be treated by the use of a G suit, which allows a team to implement all of the therapeutic modalities that are indicated and necessary. Patients with coagulopathies respond well to the gravity suit as a supporting modality.

The use of the G suit in many varied conditions that cause massive blood loss or shock has been extensively studied and reported. There are few contraindications for its use, the main ones being patients who have cerebral edema, pulmonary edema, congestive heart failure or bleeding above the diaphragm. The abdominal chamber should never be used for a pregnant patient.

Very few complications have been reported and the benefits can be lifesaving as well as reducing the amount of blood products needed and their associated complications.

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Comparative Risks of Osteoporosis and Endometrial Cancer

Cessation of ovarian function and the associated drop in endogenous estrogen levels lead to a variety of estrogen deficiency conditions such as osteoporosis, vasomotor symptoms, urogenital tract atrophy and psychological changes. At the same time, the incidence of endometrial carcinoma—a disease known to be related to estrogen use or estrogen production—increases, though the overall incidence of this disease is small. Of all estrogen-dependent diseases that are more or less specific to menopause, osteoporosis and endometrial carcinoma carry the greatest morbidity and mortality.

Osteoporosis affects up to 25% of all white women 65 years of age and older. The clinical implications of this disease are manifold: It is estimated that after age 45 years, 1 million women in the United States each year suffer fractures—700,000 are due to osteoporosis and half of these could have been prevented. In 1979 there were about 125,000 cases of hip fracture in older women in the United States. The cost of medical treatment of these fractures could be as high as $1 billion yearly and 15% of all women will die within three months after a hip fracture. There is probably more than one form of postmenopausal osteoporosis and many factors play a role in its pathogenesis, such as genetic predisposition, activity, diet and body size.

Endometrial carcinoma is the most common malignant condition of the female genital tract. Every year 39,000 new cases are diagnosed in the United States and 3,000 women die each year as a result of the tumor. Genetic predisposition, parity and body size are known risk factors in this disease.

Exogenous estrogen administration has been shown to decrease the risk of the occurrence of postmenopausal osteoporosis, but increase the chance of endometrial carcinoma. In some studies endogenous estrogen levels have been found to be decreased in cases of osteoporosis of the hip and spine, whereas in many patients with endometrial cancer the levels of these hormones were increased or they were receiving estrogen replacement. This difference in estrogen levels appears to be mediated through body stature—patients who have endometrial cancer are generally obese, whereas patients who have osteoporosis have a propensity to be slender.

The risk of both postmenopausal osteoporosis and endometrial carcinoma can be decreased by estrogen replacement therapy in combination with progestins. Gambrell in a large study found that estrogen-progestin users not only had a significantly lower incidence of endometrial cancer than those using estrogens only, but the incidence was also lower than in those using no hormones. The combination therapy appears to be at least as effective in preventing postmenopausal osteoporosis. There is evidence that progestins alone have a beneficial effect on bone metabolism.

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Genital Herpes and Vaginal Delivery

Genital herpes is thought to affect millions of women in the United States. Although more epidemiologic data are needed, the Centers for Disease Control have presented some evidence that an epidemic occurred in the 1970s. The signs and symptoms of primary and recurrent genital herpes are well known but other problems mimic this disease and misdiagnosis is common. Until recently no well-documented effective treatment has been available. Also, physicians caring for women with herpes in pregnancy have had an increasing tendency to do a cesarean section because of the severe and devastating outcome when a neonate is exposed to this virus.

Numerous purported treatments for genital herpes have been reported over the past decade but, when tested scientifically in double-blind placebo-controlled fashion, they have proved to be ineffective. Acyclovir has recently been proved effective. This antiviral drug is a purine analogue that through a complex mechanism inhibits the replication of viral DNA. Its action is quite specific and has been well documented both in vitro and in vivo to prevent replication of both herpes simplex virus type 2 and herpes simplex virus type 1, which cause about 85% and 15% of genital herpes infections, respectively. Acyclovir is available in two forms—as a topical ointment and as a sterile powder for intravenous administration. Both the topical and intravenous forms of acyclovir are licensed for use in initial episodes of genital herpes in a non-immunocompromised patient. In severe cases the most dramatic results of treatment are seen with the use of the intravenous form. In an immunocompromised patient, either form of acyclovir is indicated for use in a recurrent or an initial episode of disease, and the intravenous form is indicated in all cases of life-threatening disease. Topical acyclovir has not been proved effective in treating recurrent genital herpes. Although the patient demand for this form of therapy in recurrent herpes is great, its use should be avoided until data prove its efficacy, as there is always the risk of resistant strains developing. Oral acyclovir, which may be available in coming months, offers the hope for a more effective but less expensive therapy for primary and recurrent disease in the future.

The most severe consequence of adult genital herpes infection is neonatal acquired infection. Most commonly acquired during labor and delivery, the disease, though rare, has if untreated a mortality rate of 85% in disseminated disease and in treated neonates continued high mortality and morbidity. In one study, in 70% of cases of neonatal herpes, the mother was asymptomatic for herpes infection at delivery. Asymptomatic viral shedding during gestation has been reported to be as high as 14%. For this reason, to decrease the incidence of neonatal disease and also the need for cesarean section in mothers at high risk of disseminating herpes infection, it is recommended that viral cultures be done on a weekly basis beginning at 32 weeks gestation and from both mother and neonate at delivery. Specimens must be taken from the cervix, vagina and vulvar sites or from affected skin surfaces below the waist. Pooled specimens are advised to decrease the cost of surveillance. If lesions occur close to term, cultures should be done every other day to determine when shedding ceases. Shedding usually ceases between the third and fifth day and rarely continues beyond the eighth day in recurrent disease. In a case of active herpes, as shown either by lesions or by a positive culture in an asymptomatic patient, cesarean section is indicated.

All pregnant women should be asked appropriate questions to elicit whether genital herpes may be a problem in their pregnancy. Patients with a history of multiple partners, other venereal disease, partners with herpes infection or a history of recurrent vulvar irritation should be followed in the above fashion. If disease has not occurred previously, a patient should be encouraged to present within 24 to 48 hours of the onset of symptoms, when cultures are most likely to document the infection. Reliable tissue culture results may be obtained within five days and within 48 hours if immunoperoxidase staining is available. The findings of several clinical studies suggest that vaginal delivery may be done in about 70% of patients at high risk for harboring herpes infection who are followed in this manner. No cases of neonatal herpes have been reported in these studies.

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Vaginal Versus Cesarean Delivery for Breech Presentation

The trend toward more vaginal births in cases of breech presentation is based on recent prospective and retrospective reports indicating that in selected, carefully evaluated and monitored women, vaginal delivery carries an acceptable perinatal mortality and morbidity when corrected for congenital abnormalities and prematurity. The major morbid events related to breech labor and delivery are umbilical cord prolapse, head entrapment, cervical spine injury, traumatic delivery or extraction and the occurrence of a nuchal arm or arms. Umbilical cord prolapse occurs in less than 2% of frank breech presentations, but the risk increases progressively from complete to double footling, and is highest in the single-footling presentation. Some investigators have reported that a great proportion of the cord prolapses occur in the second stage of labor. Head entrapment is most frequently encountered in a premature breech, usually when the fetus weighs less than 1,500 grams. Because of inherent errors in estimating fetal weights, a 2,000-gram cutoff would provide a good margin of safety. Cervical spine injuries are associated with an extended fetal head and excessively forceful delivery. There is general agreement that a cervical spine-mandibular angle of 90 degrees or less is *not* extended. Traumatic deliveries or extractions are usually related to overzealous efforts for a vaginal delivery in a patient who has a less-than-totally adequate pelvis, or with labor abnormalities requiring oxytocin augmentation. Brachial plexus injury may result from the management of nuchal arms; the frequency of nuchal arms seems to be increased in the hands of less-experienced operators and when the assisted breech delivery is rushed.

The following guidelines offer a reasonable approach to selecting women with breech presentation for vaginal delivery:

- Gestational age between 36 and 42 weeks.
- Estimated fetal weight between 2,000 and 4,000 grams.
- Clinically adequate pelvis confirmed by x-ray pelvimetry.
- Fetal head not hyperextended.
- Availability and use of continuous fetal monitoring equipment.
- Normal progress of labor.
- Awareness of the risk of a prolapsed cord by the entire medical team.
- An obstetrician who is experienced in vaginal breech delivery.
- The capability to do a rapid cesarean delivery exists during the entire course of labor.
- An anesthesiologist is in attendance.

As in all medical practice, management decisions are based on an assessment of the risks and benefits of a proposed procedure or treatment. We have emphasized the perinatal risks of vaginal breech delivery, but must not ignore the increased maternal morbidity and mortality associated with cesarean birth.

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Abnormal Findings on Papanicolaou Smear: Significance and Management

There is overwhelming evidence accumulating that both the incidence of and mortality from cervical cancer are reduced by screening and treatment of the precursor lesions. Richart showed that squamous cell carcinoma of the cervix begins at the squamocolumnar junction of the transformation zone as a unifocal lesion that is generally well differentiated. The term "dysplasia" has been applied to this lesion. Depending on the degree of dedifferentiation of the cytoplasm of the dysplastic cells, the lesions are described as "mild, moderate or severe dysplasia." As the lesions enlarge, the cells become less differentiated, occupy a larger area of the transformation zone and may grow towards and into the endocervical canal. The end stages of the intraepithelial lesion are generally referred to as "carcinoma in situ." Richart prefers to call these lesions "cervical intraepithelial neoplasia, grades I, II or III" because he considers them continua of the same disease.

Papanicolaou originally reported his cytologic results as class I through V, but with the passage of time the different classes have acquired different interpretations. Cytopathologists are now reporting their results using narrative terms such as "mild, moderate or severe dysplasia and carcinoma in situ" or "cervical intraepithelial neoplasia grades I, II and III," and include other normal and abnormal findings, such as endometrial cells. The Papanicolaou smear is but a screening test, and under ideal conditions there is a false-negative rate of 5% for intraepithelial disease and of 20% to 30% for invasive carcinoma of the cervix.

Once an abnormal result is obtained from a smear, the cervix should be examined colposcopically. The location and extent of the lesions can be delineated and possible extension towards and into the endocervical canal ascertained. Distinction can be made between intraepithelial and invasive cancer and histologic correlation can be obtained by biopsy and endocervical curettage. The technique of colposcopy is described in various publications.

When the entire lesion is visible and histologic and cytologic examinations show mild to moderate dysplasia, the treatment of choice is cryotherapy or, where available, laser evaporation. When there is disease in the endocervical canal, conization of the cervix is recommended. In cases where there is severe dysplasia or carcinoma in situ (cervical intraepithelial neoplasia grade III) and the whole lesion is visible, there is controversy whether cryotherapy or laser evaporation is appropriate, as the incidence of residual disease or subsequent invasive cancer seems higher than in those treated by conization.

The American Cancer Society has recently recommended changing the screening from one to three years, but the American College of Obstetricians and Gynecologists disagrees and recommends annual smears for all sexually active women because the risks of invasion in patients with undetected carcinoma in situ, or cervical intraepithelial neoplasia, increases exponentially as the interval between cytologic examinations increases.

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Human In Vitro Fertilization and Embryo Transfer

The extracorporeal fertilization of mammalian oocytes was first reported more than 20 years ago. Since that time more than ten different species of mammalian oocytes have been successfully fertilized in vitro. In the past three years, reports of successful human in vitro fertilization and embryo transfer have been received from England, Australia and the United States. The use of an in vitro fertilization and embryo transfer system to deal with various factors encountered in infertility situations is becoming more common.

Currently clomiphene citrate or human menopausal gonadotropin (Pergonal) therapy is used as the primary method to stimulate multiple follicle development and indirectly help time laparoscopic oocyte recovery. In conjunction with ovarian stimulation, patients have daily ultrasound scanning of the ovaries and serum specimens are taken for measurement of estradiol levels. Before laparoscopic aspiration, human chorionic gonadotropin is given to initiate final maturation of the oocyte.

With the use of ovarian stimulation and intravenous administration of human chorionic gonadotropin, it has been shown that laparoscopy should be done 36 hours from the time of the latter injection. The laparoscopy is done using general anesthesia and routine laparoscopic techniques. A special oocyte-aspirating system is currently being used in which a 14-gauge needle with an interlining of 18-gauge Teflon goes into a fluid trap and is connected to a wall suction set at about 150 mm of mercury negative pressure. By monitoring with combined ultrasonic and hormonal methods and with the Teflon-lined aspirating system, we are able to recover oocytes in about 85% of the follicles aspirated.

About five hours after the laparoscopic recovery of the mature oocyte, the husband is asked to produce a semen specimen. After preincubation of the sperm, 50,000 motile cells are then added to the plate containing the oocyte. At about 40 hours from the time of fertilization, the oocytes are inspected and at this time four-to eight-cell embryonic development should be observed. Once normal embryonic development is seen, transfer back into the patient's uterus is undertaken, using a Teflon catheter system.

Work on the human in vitro system began early in 1970; however, pregnancies have occurred only within the past five years. The overall pregnancy rate in any given program is about 15% to 20% of patients treated. The problems we face today with this fertility procedure are slowly being solved. The techniques that may become applicable in the near future are ultrasound-directed, needle aspiration of mature oocyte, thus alleviating the need for general anesthesia and laparoscopic aspiration. Moreover, with growing evidence of successful cryopreservation techniques in animals, the possiblity of human embryo cryopreservation may become a reality. These techniques appear viable but must be tested extensively before they are available for use in humans.

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The Use of Ultrasound in Infertility Management

Estimates are that one out of every six couples requires medical assistance to achieve pregnancy. For most of these, where no pathologic condition exists, precise timing of ovulation is the most critical element for success. Whereas the use of drugs such as clomiphene citrate (Clomid) or menotropins (human menopausal gonadotropin [Pergonal]) often better define the ovulatory period, the more conventional measures rely upon basal body temperature charts, cervical mucus examination and previous menstrual history as guides. In some cases, hormone assays like rapid estradiol or luteinizing hormone have been of great use; even when all of these measures are used accurately, however, predicting the time of ovulation can be a significant clinical problem. Because the viable lifespan of a human ovum is 16 to 18 hours and preceding fertilization the sperm must undergo a four-to six-hour transformation termed capacitation, precise timing becomes critical.

This problem has been substantially eliminated in the past two years through in vitro fertilization programs and application of real-time ultrasound as a means of timing laparoscopic recovery of ova. Using a full-bladder technique, ovaries and their developing follicles can be readily defined in transverse and longitudinal planes. Follicular growth proceeds at a rate of 1 to 3 mm a day, with a rapid growth spurt possible some 24 to 36 hours before ovulation. Follicles are considered to be functionally mature when their maximal diameter is 18 mm or more. Follicles of this size will respond to ovulation doses of human chorionic gonadotropin (5,000 to 10,000 IU) within 12 to 36 hours after intramuscular injection.

Ultrasound used in this manner does not replace more conventional measures of impending ovulation, but it does hold the promise of better understanding of a given patient's ovarian response to natural or drug-induced signals. Completed studies suggest that its use increases pregnancy rates while shortening course of treatment.

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Changing Views on the Management of Vaginitis

There have been a number of significant advances in the treatment of infectious vaginitis in the past five years, not only through the introduction of new drugs but also by using existing drugs for new indications. In view of the fact that the three major types of vaginitis are all to some extent sexually transmitted, it is likely that the number of women seen with complaints referable to vaginitis will continue to increase.

The most common cause of infectious vaginitis is *Gardnerella vaginalis* vaginitis, previously called *Haemophilis vaginalis* vaginitis or nonspecific vaginitis. The infection is characterized by a profuse, homogeneous, adherent gray discharge that is associated with a "fishy" odor and a minimum of irritative symptoms. Although the laboratory diagnosis has relied on recognition of "clue cells" in the saline wet mount, another helpful diagnostic maneuver is the "odor" or "amine" test in which the odor of the discharge worsens upon adding 10% potassium hydroxide solution to the residue on the posterior blade of the speculum. Treatment has traditionally consisted of topically applied sulfa creams or oral tetracycline, but it is now generally agreed that these measures are relatively ineffective and that the agent of choice is metronidazole, 500 mg given twice a day for seven days to both the patient and her partner. In patients in whom metronidazole is contraindicated (such as pregnant women), cephalexin or ampicillin, 500 mg given four times a day for seven days, are secondary drugs of choice. A contrary opinion was recently given by Robbie and Sweet when they reported their reservations regarding the extensive and repetitive use of metronidazole because of its possible mutagenicity and carcinogenicity when more innocuous methods are available. They suggest that local preparations or ampicillin be used as the treatment of choice and that metronidazole be reserved for initial treatment failures.

Women with monilial vaginitis usually have vaginal and vulvar itching and burning and a nonodorous white vaginal discharge. Diagnosis is made on the basis of identification of pseudohyphae on a 10% KOH slide or with a positive yeast culture. Nystatin, which had previously been the drug of choice, has now been replaced by the more effective synthetic imidazole fungicides, clotrimazole and miconazole nitrate, which are available as creams, vaginal tablets and suppositories. Although standard therapy consists of a daily application for seven days, a recent study has shown equivalent results with twice-a-day therapy for three days, thereby giving patients a choice of regimens.

Trichomonas vaginalis vaginitis presents as vaginal itching and burning in conjunction with a foul-smelling watery discharge. Diagnosis depends on the identification of motile trichomonads on saline wet prep or a positive Diamonds culture. The mainstay of treatment continues to be metronidazole, though recent studies have shown that a 2-gram single dose is as effective as the more standard seven-day course. Because of improved compliance and minimization of the duration of side effects, most authors consider the single-dose regimen, given to both patient and partner, to be the treatment of choice for vaginal trichomonas.

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Glucocorticoids and Lecithin-Sphingomyelin Ratio

The antenatal use of glucocorticoids to prevent respiratory distress syndrome in premature infants has accelerated over the past several years. The rationale for their use is based on several studies done of humans and animals that have shown the following: (1) Exogenously administered steriods accelerate the normal pattern of lung development, including the accumulation of lamellar bodies in type II cells and the production of alveolar surfactant. In humans, glucocorticoids decrease the incidence of respiratory distress syndrome and increase survival rate for premature infants. (2) Most likely increasing concentrations of endogenous corticosteroids in an undisturbed or a stressed fetus influence lung development in the same manner as exogenously administered steroids. (3) When exogenously administered glucocoricoids are used in dosages that do not elevate fetal cortisol concentrations beyond that seen with physiologic stress responses, they present little risk to an infant. (4) Morphologic, functional and biochemical variables of lung development are more closely correlated to cortisol concentrations than is fetal age.

Although the lecithin-sphingomyelin ratio in amniotic fluid has proved to be a reliable index of fetal lung maturity, the amniotic fluid “lung profile” can more accurately predict fetal lung maturation in humans. Several studies have shown an increase in lecithin-sphingomyelin ratio after exogenous glucocorticoid administration, whereas others failed to do so, albeit noting a significant reduction in the incidence of respiratory distress syndrome and increased fetal survival. The latter findings suggested that either adequate amounts of surfactant should be present in alveoli before their appearance in amniotic fluid or that qualitative alterations in surfactant composition not reflected by the lecithin-sphingomyelin ratio have occurred. Recent findings in alloxan-treated animals show that exogenously administered glucocorticoids increase phosphatidylglycerol synthesis and reverse the functional delay in fetal lung maturity, with no significant change if surfactant content or the lecithin-sphingomyelin ratio. The above findings attest to the added advantage of using an amniotic fluid “lung profile” specifically in those clinical situations—such as a case of diabetes mellitus with no vascular involvement and Rh immunization—wherein delayed lung maturity is expected.

Studies of surfactant metabolism show that maximal beneficial effects of glucocorticoids are obtained after 36 hours of administration. Also, for continued benefit, the same dose should be repeated seven to ten days later. Of great interest are the recent observations that fetal responses to glucocorticoid administration are influenced by sex and ethnic origin.

I recommend that the use of glucocorticoids for fetal lung maturity be limited to women in premature labor whose amniotic fluid analysis is not available, or is in the immature range, and whose labor can be delayed for at least 36 hours; where immediate delivery is indicated (that as, in cases of severe hypertension or abruptio placenta), glucocorticoid administration is contraindicated. More studies are needed to define optimal mode of drug delivery, dosage, short-term maternal risks and the long-term effects on neonatal central nervous system and immune systems.

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Immunologic Thrombocytopenia in Pregnancy: Predicting Fetal-Neonatal Risks

Immunologic thrombocytopenic purpura is a relatively uncommon disorder whose occurrence in the general population includes a significant number of women of childbearing age. As a result, obstetricians can be faced with the problem of managing such a patient during a pregnancy.

Earlier reports had suggested an increase in maternal mortality rates as high as 14%. Similarly, perinatal death rates of 15% to 25% had also been reported, related at least in part to thrombocytopenia in neonates. This background information, as well as the absence of any more sensitive laboratory evaluation than maternal platelet count, probably contributed to the recommendation of a "prophylactic" cesarean section when the maternal platelet count was less than 100,000 per μl. More recent studies, however, that examined the immunologic mechanisms of this disorder and their application in pregnant patients, have resulted in a more selective use of cesarean section in such patients.

Immunologic thrombocytopenic purpura is caused by antiplatelet antibody of the subclass 3 of immunoglobulin G. As well, there appear to be placental receptors for the Fc portion of the IgG molecule that can account for active transport of antibody to the fetal circulation. The level of antiplatelet antibody can be measured in maternal serum with respect to both free circulating antibody and bound, or platelet-associated, antibody. In addition, the latter techniques can still be used whether a patient is in remission or has active disease, and whether or not she is receiving steroids.

In 1982 Cines and co-workers examined levels of free and associated antiplatelet antibody in 23 pregnant women. While the maternal levels of platelet-associated antibody did not correlate with thrombocytopenia in their neonates, the levels of circulating antibody were elevated in 11 women, 9 of whom had thrombocytopenic neonates (defined as having a platelet count of less than 150,000 per μl). Further, the mothers who had the highest levels of circulating antibody had the more severely affected neonates (a platelet count of less than 30,000 per μl).

In 1983 Scott and associates similarly examined circulating antiplatelet antibody levels. While they found thrombocytopenic neonates in mothers with elevated antibody levels, they also noted affected neonates in mothers whose levels were normal. They therefore also used fetal scalp blood platelet counts in 25 patients and correctly identified the five thrombocytopenic infants (platelet count less than 50,000 per μl) with no complications from the technique in any of the infants.

From these reports, it would seem that cesarean section in mothers with immunologic thrombocytopenic purpura should be "selective" rather than "prophylactic" except for other usual obstetric indications. Such mothers should be evaluated for elevated circulating antiplatelet antibodies to determine the range of risk for neonatal thrombocytopenia. Further, at 3 cm of dilatation, fetal scalp blood for platelet count should be obtained and, following Scott's recommendations, physicians should select cesarean delivery of fetuses whose platelet count is less than 50,000 per μl and allow vaginal delivery when the count is more than 50,000 per μl.

Maternal bleeding complications at cesarean section are unlikely with platelet counts of 30,000 per μl or more. In mothers whose counts are less than 20,000 per μl, immediate preoperative platelet transfusions should minimize the risk of hemorrhagic problems.

William R. Crombleholme, M.D.

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An Updated Approach to the Diagnosis of Ectopic Pregnancy

Diagnosing ectopic pregnancy is difficult and the problem is missed by the initial examining physician in up to 70% of cases. The correct diagnosis, which is typically made at the time of rupture, is usually delayed for two to three weeks after a patient seeks medical attention.

In an effort to diagnose ectopic pregnancy earlier—that is, before rupture—an updated approach using the combined results of the highly sensitive serum radioimmunoassay pregnancy test and ultrasound is required. The advantages of the radioimmunoassay test over the more frequently used immunologic pregnancy test include its increased sensitivity and specificity (lack of false-positive and false-negative results) and the ability to quantitate the precise level of human chorionic gonadotropin (HCG).

Ideally, an ultrasound study should be done in patients in whom the results of the pregnancy test are known.

Uterine changes are the key feature for deciding whether the pregnancy is intrauterine or extrauterine. Recent evidence suggests that it is possible to differentiate an abnormal intrauterine pregnancy or a decidual reaction of an ectopic pregnancy from an early normal intrauterine pregnancy with about 98% confidence by identifying "double decidual lines" in patients who have a normal intrauterine pregnancy. Patients with intrauterine fluid who lack this finding have either an ectopic pregnancy or an abnormal intrauterine pregnancy.

Adnexal changes are difficult to assess in patients who have suspected ectopic pregnancy because it is not usually possible to be certain that a visualized adnexal mass represents the ectopic pregnancy. Similarly, cul-de-sac fluid is also a nonspecific finding and can occasionally be due to a ruptured or hemorrhagic corpus luteum cyst.

If the ultrasound findings and HCG determination are suspicious but not diagnostic for ectopic pregnancy, a variety of tests may be required, including serial HCG determinations, repeat ultrasound examination, uterine dilatation and curettage, culdocentesis or laparoscopy.

Faye C. Laing, M.D.

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Precautions: When discontinuing Catapres (clonidine hydrochloride), reduce the dose gradually over 2 to 4 days to avoid a possible rapid rise in blood pressure and associated subjective symptoms such as nervousness, agitation, and headache. Patients should be instructed not to discontinue therapy without consulting their physician. Rare instances of hypertensive encephalopathy and death have been recorded after cessation of clonidine hydrochloride therapy. A causal relationship has not been established in these cases. It has been demonstrated that an excessive rise in blood pressure, should it occur, can be reversed by resumption of clonidine hydrochloride therapy or by intravenous phentolamine. Patients who engage in potentially hazardous activities, such as operating machinery or driving, should be advised of the sedative effect. This drug may enhance the CNS-depressive effects of alcohol, barbiturates and other sedatives. Like any other agent lowering blood pressure, clonidine hydrochloride should be used with caution in patients with severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease or chronic renal failure.

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1. Pioneering Research in Hypertension: The Role of the Sympathetic Nervous System, film and monograph, Boehringer Ingelheim Ltd., 1982.

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Physicians and the Hospital: An Expanded Managerial Role Expected with Diagnosis Related Group Based Hospital Reimbursement

LAURENCE F. MCMAHON, JR., M.D., M.P.H.

ABSTRACT—The rising cost of medical care and, in particular, hospital care has precipitated a fundamental change in hospital reimbursement. The new prospective method of hospital reimbursement is based on individual rates for groups of medically similar patients and is called reimbursement by Diagnosis Related Group (DRG). This new reimbursement strategy has been adopted nationally for Medicare reimbursement.

It is expected that the patient-oriented DRG prospective reimbursement will lead to changes in the organizational structure of the nation's hospitals. In order to have its desired impact in decreasing the rise in hospital costs, DRG reimbursement must foster new administrative reporting systems that link the financial implications of patient care with the practitioners who deliver that care. Such management information systems should foster a rapid increase in the involvement of physicians in the administrative affairs of hospitals. By this involvement physicians may help to insure the quality of care for their patients. The beginnings of increased physician involvement has been noted in New Jersey, the first state to adopt DRG reimbursement for all payors.

Introduction

The rising cost of medical care has occasioned a reappraisal of the health care system. This analysis has tended to focus on hospital care because forty percent of all health care costs are centered in these institutions.[1] The additional fact that hospital care has increased at three times the average rate of inflation has added a sense of urgency to this review.[2]

Hospital administrators and physicians traditionally have had rather separate areas of responsibility and expertise. The administrator's duties involve the organization and management of services and staff to aid physicians in the care of patients. Physicians, on the other hand, have been concerned solely with patient care. These roles evolved from a hospital system that was primarily custodial in nature. In the early part of this century there were few effective treatments, and hospitals were often a place indigent patients went to die.

Over the past thirty years we have witnessed a revolution in medical practice and technology. This revolution has brought the advent of CT scanners, renal dialysis, chemotherapies, open heart surgery, etc. No one would argue the fact that these advances in medical care have dramatically improved our ability to aid patients. If there is a dark cloud in this picture, however, it is the costs associated with many of these advances. Improvements in medical practice have not come without dramatic increases in its costs. The changing role of medicine during this century from largely supportive to therapeutic has also changed the role of hospitals. No longer are hospitals a place to die, but increasingly, they are places one goes to be treated with the prospect of being cured.

The systems developed to pay for hospital care evolved during the hospital system's early years. The traditional method of reimbursement is to pay hospitals a daily bed rate negotiated by each large third party payor with each hospital and to pay on a fee-for-service basis for the diagnostic and therapeutic modalities used by each patient. In addition, payment was retrospective, with the bill

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calculated after the patient was discharged. One can see that based on a custodial model, where such resource intense interventions were relatively infrequent, that this seemed a reasonable approach, as most costs were linked to the hospital's custodial function. However, the growing complexities of medical care and the increasing resource intensive treatments have made this reimbursement methodology as archaic as the medicine that was practiced at the time it was adopted.

Hospital Case Mix

Over the past ten years research in hospital case mix has clearly shown that all hospitals are not the same in terms of the types of patients they treat.[3,4] The average patient day reimbursement rate, therefore, represents some composite of the actual cost at each hospital, based on its average patient mix. The problem of determining equitable reimbursement formulas is compounded by the fact that not only are the mixes of patients among hospitals different, but also that the mix of diagnostic and therapeutic modalities used to care for a particular type of patient differ even at a given hospital.

Given this fact, and the growing cost of health care, it became clear that a new method of reimbursement was needed to 1) reflect these case mix differences among hospitals in order to ensure more equitable reimbursement and 2) provide patient care related data to allow for a more substantive dialogue among administrators and physicians. It was hoped that such a system would provide incentives to hospitals to decrease the rising cost of hospital care, as well as provide incentives for physicians to review patient care within an institution. The system that subsequently evolved is called reimbursement by Diagnosis Related Group (DRG).

Diagnosis Related Group Reimbursement System

In order to construct a reimbursement system that reflected both the case mix differences among hospitals, as well as provided medical information on the patients treated at an institution, there were three characteristics necessary in initial group definition.

1. That patient groupings must be manageable in number;

2. That the system be based on available medical and demographic data. (This decision was based on the cost of developing new systems of data collection. Therefore, the medical and demographic data was limited to that available on the Uniform Hospital Discharge Dataset.);

3. That the groupings of medically similar patients would also define statistically stable groups in terms of the use of hospital resources. (The resource initially used was length of stay.)

After forming groups based upon both statistical analysis as well as physician review of the clinical grouping process, a further step was necessary in order to use these groups for reimbursement purposes. The additional analysis felt to be necessary was;

4. That each Diagnosis Related Group was evaluated to determine its associated cost, and the costs were allocated using a standard chart of accounts. In this way each DRG had associated with it a cost profile.

Thus, a system was developed that was diagnosis based, and could be used for hospital reimbursement. A hospital's total reimbursement would be based on the number of patients in a given DRG multiplied by the cost associated with that DRG, summed over all the DRGs at that hospital. Because this reimbursement is defined by the type of patient treated at the institution, it controls for case mix and it provides a natural focus for further discussion and analysis, in which both the administration and the medical staff could participate. This DRG based prospective reimbursement system has been adopted as the means of reimbursing Medicare patients nationally.[5] (A full discussion of this grouping process and the extensive physician involvement in group definition is beyond the scope of our current discussion. However, a number of recent articles discuss this process at length.)[6,7]

In order for the DRG approach of hospital reimbursement to have its desired impact on the rise in the cost of hospital care, it must foster a dialogue between the administrators and the medical staff. It is the care provided to the physician's patients that generate the majority of hospital costs. Therefore, a review of that care must be undertaken to effect any change in those costs. In addition, such medical review is necessary to ensure the quality of medical care. This medically oriented review is, necessarily, the responsibility of the hospital's medical staff. The hospital's administration, however, must be able to highlight groups of patients and/or physicians who are likely to offer fertile ground for subsequent medical analysis. In addition, physicians at a hospital should be able to anticipate changes in medical practice (e.g. NMR scanners) that are likely to affect patient care and therefore hospital costs.

For this dialogue to occur, hospitals must be able to provide financial data in a format that conforms to the administrative structure of the institution as well as financial data that is linked to diagnostic information with which physicians are familiar.

Management Structure of Hospitals

The traditional hospital managerial structure is organized by cost and revenue centers. Thus, an individual assistant administrator might have administrative authority for the laboratory, x-ray, and out-patient services, while another assistant might have administrative responsibility for the maintenance department, dietary department, etc. It is easy to see that this fragmented administrative authority is the antithesis of the patient care related integrative approach of the Diagnosis Related Group reimbursement system. Yet, it would be naive to assume that the organizational structure of the hospital industry would suddenly change to accommodate new DRG based management data. Therefore, financial reports must be able to conform to a hospital's existing organizational framework. In addition, these reports, must also support the integrity of the DRG defined hospital patient mix.

Clinical Structure of Hospitals

The medical staff structure of a hospital is more feudal than managerial in nature. The large divisions of medicine, surgery, pediatrics, etc., represent the general organizational divisions of the medical staff. In addition to these divisions, in large institutions, there may be further subdivisions by subspecialty sections. In this setting, it is the subspecialty chiefs who have direct supervisory authority within their individual sections. This highly fragmented structure is most apt for large institutions. As institutions become smaller, these sharp divisions become somewhat blurred, although the major divisions of medicine, surgery, etc., are still applicable.

Linked Administrative Medical Management Information System

In order for the DRG based hospital reimbursement system to realize its full potential in introducing appropriate incentives to hospitals, these two managerial styles must be accommodated. The administrative staff must receive reports that are cost center based and that can be used to highlight trends and changes by cost center. The medical staff must have reports that reflect clusters of diagnosis and treatment modalities used by a clinically coherent class of patients so as to focus on areas for medical review. In addition, these information systems must also be able to project the financial consequences to the hospital of changes in medical practice and/or case mix.

In order to have these desired outcomes, such hospital information systems are likely to require two major components; the first is a computer based structure that has the flexibility to display the hospital's financial information in different formats to accommodate both administrators and physicians; second is a medical staff that acknowledges the need to become involved at this interface between the delivery of medical care and its associated costs and revenues.

The first task is a relatively straightforward, although not a simple undertaking. A substantial effort must be expended to develop useful management information systems that have the flexibility of reporting financial and medical data using formats that conform to the existing administrative organization as well as the medical staff structure.

An example of a possible reporting system may be helpful to highlight the proposed interaction between the administration and the medical staff. As mentioned above, the administrative structure of the hospital is one of cost and revenue center based authority, e.g., the radiology cost center. The administration is primarily interested in changes in costs from one year to the next in order to plan the hospital's staffing requirements, capital needs, etc. In a DRG based system these changes in the radiology cost center would be reported as a function of a given DRG.

For example, DRG 21, viral meningitis would have associated with it an average radiology cost. If its associated radiology cost increased by twenty percent over one year, the responsible administrator would need to know the reason for the increase in order to adjust the budget. Was the increase because; 1) more patients in the group had radiologic procedures, but of the same intensity as the year before (i.e. one year 20% of group had chest x-ray, in second year 50% of group had chest x-ray); 2) did the mix of radiology tests in the department change so that the costs in the radiology department increased as a whole and thus the cost associated with each test increased; 3) is there an increase in the intensity of radiology procedures (e.g. use of NMR head scans); 4) or have unnecessary radiology procedures been performed on this group of patients? Clearly many of the questions which must be answered to help understand the observed change in costs are purely administrative in nature. Just as clearly, however, there is an overlap with the medical management of this group of patients and the effect different clinical management strategies have on these patients' associated costs.

In the example above, if the administration is unable to explain the increased costs of radiology for this group of patients after controlling for departmental cost changes (etc.) they will need to consult with the appropriate medical staff who care for this group of patients in DRG 21. To expedite this process, the computer based reporting system must be able to identify the medical specialty responsible for a DRG and to present the financial data in the diagnosis based format to appropriate medical staff members.

After review of the DRG, the medical staff should be able to explain the change of resource use for this group of patients. This would likely involve one of two possibilities: 1) the appropriate medical staff, after review, felt that they had overutilized the resource, or 2) there was a justifiable medical reason for this change. In the latter case the medical staff would assist the administrators to prepare documentation of this fact, to appeal for higher reimbursement rates for this group of patients. This type of patient care review, although initially financially motivated, will provide opportunities for discussion and analysis of patient management. Such analysis is expected to assist in maintaining quality medical care.

The second necessary component for the successful implementation of programs capable of slowing the rise in hospital costs, is a medical staff that acknowledges a degree of responsibility in evaluating patient care and the financial implications of that care. As noted previously, the change from a custodial hospital to an interventional system has dramatically increased the services medicine can offer patients. Coupled with these advances has been a rise in costs. Physicians must not take credit, both intellectual and financial, for medicine's advances without also acknowledging a certain responsibility in evaluating hospital care from both a quality and a financial viewpoint.

Management Role for Medicine

A system that links the reimbursement of hospitals with the mix of patients treated appears inevitable. Coupled with such systems is the need for medicine to take an active role in not only managing patient care but also managing the instruments of that care. No longer can these decisions be placed solely in the hands of administrators, regulators, or third party payors devoid of patient care experience and responsibility.

For large institutions this means that chiefs of service and subspecialty chiefs will have increasing administrative responsibilities, not only in administering their department, but also in evaluating the care delivered by the members of that department. At smaller hospitals these types of review will need to be conducted by the medical chief in cooperation with the medical staff. Such largely ceremonial positions will, obviously, require some remuneration to compensate for this increase in responsibility.

A recent review of the organizational impact of the DRG based hospital reimbursement system in New Jersey (a different system than that adopted for national Medicare reimbursement) has shown just this type of increased medical involvement in the hospital's administration. A recent organizational evaluative study found that in DRG hospitals, "Four of six DRG hospitals have started to use the services, for salary or stipend, of a medical director (2), director of medical education (1) or a salaried chief of staff (1). There is no change in the managements in non-DRG hospitals."[8] Additionally, this analysis which compared DRG hospitals with non-DRG hospitals in New Jersey showed that thanks in part to "the expanded use of managers and educators of the medical staff in the DRG hospitals, it seems fair to conclude that DRG reimbursement has had a positive effect on the involvement of the medical staff in the DRG hospitals. Medical staff interviews bear this out."[9]

The DRG organizational evaluation noted further that "Program budgeting and especially program management (with clinical chiefs being fully responsible for the management of resources going into each program) are examples of changes in the technical core [hospital organization] itself."[10] Thus, in this initial study of the organizational impact of DRG based hospital reimbursement, Boerma foresees increasing direct administrative responsibility for the clinical chiefs.

Future Research

Although medicine has undertaken some research in evaluating technologies and patient care, this activity has been rather meager in comparison to the monies and effort spent in basic science research. This lack of research has contributed, in part, to the hospital's current financial crisis. Medical faculties will, therefore, need to encourage physicians who can incorporate hospital based patient care with hospital based cost and quality research just as they now support positions for faculty who engage in patient care and basic science research. Research in patient management, evaluation and quality assessment will assist both society and more particularly the physicians across the country who will need to review these problems in the nation's hospitals.

It is expected, therefore, that this expanded managerial role for medicine will have a direct impact on the evaluation of patient care in our hospitals. Without the active participation of medical practitioners assisting in the development of patient centered review and reimbursement systems, it is feared that less patient oriented reimbursement strategies (e.g. caps) will be adopted. The structure of the management information system as outlined above, is expected to facilitate this physician involvement in both hospital operations and patient care evaluations.

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The Origins of Anesthesia

SHERWIN B. NULAND, M.D.

Introduction—There is no more fascinating story in the annals of medical history than the intriguing tale of the discovery of inhalation anesthesia and the events leading up to it. *The Origins of Anesthesia,* published in June of 1983 by the *Classics of Medicine Library,* chronicles these events and reproduces in facsimile the seminal journal articles as they apply to the narrative retelling. The book's author is the Literary Editor of *Connecticut Medicine,* Dr. Sherwin B. Nuland. Through the kind permission of the publisher, Gryphon Editions of Birmingham, Alabama, successive chapters from the book will be published in *Connecticut Medicine* over the course of the next few issues.

PREFACE

Attempting to solve the problem of assigning priority for the discovery of inhalation anesthesia can be muddling to the mind and scrambling to the senses. To produce a confusing pandemonium of names, dates, claims, and pronouncements would be an exercise in futility, resulting only in yet another literary monument to the human predisposition to contentiousness and rancor. Our aim is otherwise. Although it is patently impossible to tie up all of the loose ends in such a way as to produce an uncomplicated narrative, we have chosen a simple star by which to steer this re-telling, and used that eminently acceptable and easily visible luminosity to guide the direction of the narrative: almost no one would deny that the single crowning moment in the history of anesthesia occurred at the Massachusetts General Hospital on October 16, 1846, when William Thomas Green Morton demonstrated the effectiveness of ether. At that instant, surgical anesthesia began its existence; everything that led up to it was prologue, everything that was tangential to it was byplay, and everything that followed it was amplification.

The purpose of this book is to relate the events leading up to that day—the prologue, the byplay, the ultimate dramatic moment, and the direct consequences to those who were involved. Because any description of the era of gestation and birth of inhalation anesthesia would be incomplete without recounting James Y. Simpson's introduction of chloroform, we have added that intriguing chronicle as well. From that point on, the true infancy of the craft begins, as physiological observations and pharmacologic findings came forth, and as technology and instrumentation gradually created a sophisticated new specialty. By ending our story with Simpson, we have stopped just short of John Snow, who took the concept of anesthesia from its inventors and carried it, like an ever more brilliant torch, to its most practical uses.

Perhaps in reviewing the sources we have chosen to present in facsimile in this volume, individual readers will arrive at different assessments of the importance of the contributions made by the various participants in the saga. But no one who becomes at all familiar with this most dramatic of all journeys into medical progress can fail to grasp the unchallengeable truth that everything came to a focus on that October morning. Progress radiated from that place and time with a confounding rapidity the like of which had never before resulted from any single scientific event. In fact, even supporters of the claims of others recognized that of all the immense volume of material ever published in the field of pain-free surgery, there are four papers which must be regarded beyond doubt to be the writings which established the basis of credibility that led to modern anesthesia. They are all related to the events that took place on October 16, 1846, and they can be found in this volume between pages 68 and 94.

But long before Morton and the Ether Dome, and long before the ultimately tragic events that surrounded the birth of anesthesia, there was mystery and there was romance and there were the magical adornments of literature. For, ever since awareness first gleamed in the slowly awakening mind of man, he seems to have sought its opposite, either to produce a primeval painless unconsciousness or to find a world of fantasy more caressing than the often grim realities of his daily life. Whether to induce senselessness in self or others, ancient, medieval, renaissance and modern men have been entranced by the possibilities of slumber and its accompaniments. And so this work will begin by describing mankind's earliest known attempts at inducing sleep. We must be forgiven if we sometimes intermix the real with the fantastical, and the fictional with the documented—our ancient sources are less scrupulous with such things than are modern scholars. But the basic thread of the story and most of the details have a firm foundation in reality—the potions existed, much as they are described in the selections reproduced here, and if they did not always accomplish what was claimed for them, they and

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their chroniclers have left us with a set of priceless images of flirtations with insensibility, and of dreamworlds in which the historiographer and the poet dance to each other's most enchanting music.

This volume has been produced in the Historical Library of the Yale School of Medicine. It was from this magnificent collection of books that John F. Fulton and Madeline E. Stanton compiled "The Centennial of Surgical Anesthesia" in October, 1946, which was an annotated catalogue of their exhibit of publications bearing on our topic. Combining as it does the work of Dr. Fulton, who was one of the world's most produtive medical historians, and of Miss Stanton, the *mater et magistra* of several generations of historical researchers, this small volume, with its pithy commentary and superb scholarship, remains one of the gems of annotated bibliography. We have leaned heavily on it as a guide and as a source of inspiration. It is most appropriate, therefore, that we dedicate the present volume to the memory of those two scholars, whose names will always be so strongly linked in the recollections of contemporary medical historians, John Farquhar Fulton and Madeline Earle Stanton.

The Anodynes of Antiquity

Not poppy, nor mandragora,
Nor all the drowsy syrups of the world,
Shall ever medicine thee to that sweet sleep
Which thou ow'dst yesterday.
—*Othello,* Act III, scene III.

The ability to produce a state of general obtundation has been a practical necessity to all societies. Until relatively modern times the methods of achieving it have been either herbal, psychological, or a combination of both. The physician-botanists of the 17th and 18th centuries were the heirs to a tradition as old as mankind itself, which reached its flower, so to speak, in the search for those plants which could be shown to effect the state of consciousness. Although the nature of the drugs producing the desired outcome had to await elucidation until the development of laboratory science, some of modern-day medicine's most commonly used narcotizing agents were well-known to Greek and Roman healers. The drugs used prior to the modern period were, principally, the poppy, the hyoscyamus, the mandragora, and of course, alcohol.

POPPY

Opium, called tears of poppy, was derived from the sap (tears, or lacrimae) obtained by cutting the unripe seed-pod of the plant. The drops of milky juice which came forth from the cut pods were collected in a shell or dish and allowed to dry in the sun. The substance was well known in ancient times, and was used by many prominent physicians for centuries before our own. The writers of antiquity commonly referred to poppy-induced sleep with a term used by Virgil: *Letheon.* Two thousand years later, the word surfaced again, this time as the name given by William Morton to sulfuric ether so that the true nature of his discovery might be kept a secret. The subterfuge was soon abandoned, but the term Letheon persisted in Morton's writings, to confuse students of medical history ever since.

From Aurelius Cornelius Celsus we have a clear description of the use of tears of poppy and of one method of preparation. The writings of Celsus (First Century A.D.) represent the oldest medical document that we have after the Hippocratic Corpus. The works attributed to him were a compilation of treatises on medicine and other subjects, written for the aristocracy of his time. Because of the excellence of Celsus' literary style in Latin, his eight volume *De re medicina* was one of the most widely read scientific works of the Renaissance "Revival of Learning," and it has since become an excellent source of knowledge of Greek medicine, drawing heavily as it did upon Hippocratic or post-Hippocratic sources. Celsus describes what he refers to as "anodyne pills," which relieve pain, and writes of them:

> *Those pills which alleviate pain by causing sleep are called anodynes in Greek. It is bad practice to employ them except in cases of urgent necessity, for they are compounded of powerful drugs and are bad for the stomach. However, one may be used, which contains a denarius each of tears of poppy and galbanum, and two denarii each of myrrh, castoreum, and pepper. It is enough to swallow a piece the size of a bean.*

Celsus describes a method of pill preparation and several appropriate uses of the agent:

> *Take a handful of poppy when it is ripe for taking its tears, put it into a vessel, add enough water to cover it, and cook it. When it is well cooked, squeeze out the mass of poppy into the vessel before discarding it, and mix with the fluid an equal quantity of raisin wine. Boil it until it thickens, then cool it and make it into pills about the size of domestic beans.*
>
> *They have many uses. They induce sleep, whether taken alone or dissolved in water. Added, in small quantity, to the juice of rue, or to raisin wine, they stop ear-ache. Dissolved in wine, they stop colic. Mixed with beeswax and attar of roses, and with a little saffron added, they cure inflammation of the vulva; and dissolved in water which is then applied to the forehead, they stop running of the eyes.*
>
> *In the same way, if a painful vulva prevents sleep, take two denarii of saffron, one each of anise and myrrh, four of poppy tears, eight of hemlock seeds, and mix them into a paste by adding old wine. The dose is a piece the size of a lupin, dissolved in three glasses of water. But it is dangerous to administer when fever is present.*

It has been theorized by some that the "drug which quenches pain and strife and brings forgetfulness of every ill" prepared by Helen, daughter of Zeus, in the

Odyssey, was opium. Whether opium or some other anodyne, it is likely that Homer's reference to "such cunning drugs, . . . drugs of healing" was not fanciful, for the probability is high that even in those early times, the poppy was being used as a source of relief from physical and emotional pain. The literature of the succeeding 3,000 years is rich in its references to sleeping potions.

MANDRAGORA

Considering the wondrous and mystic qualities that have sometimes been attributed to it, it is with some hesitation that we point out that the mandrake (*Mandragora officinarum*) is a member of the humble potato family. The plant has a short stem, with a root which is often forked, and a berry-like orange fruit, sometimes referred to as the apple. The preferred source of the alkaloid was the root, followed in favor by the apple, and then the leaves. Because the forked root can, with some imagination, be thought to have the appearance of the lower half of a human body, the plant was often used as a love potion, and it is still employed today in some parts of the world as a means of enhancing the possiblity of conception. Western literature contains numerous allusions to its powers, but the most familiar reference to the plant is probably John Donne's outburst concerning the futility of seeking a steadfast love, which he illustrates by a list of other impossible tasks:

Go, and catch a falling star,
Get with child a mandrake root,
Tell me, where all past years are,
Or who cleft the Devil's foot.

The fact that mandragora contains alkaloids of the belladonna group explains its effectiveness as an anesthetic agent. Philemon Holland's translation of Pliny's *Historia Naturalis* (A.D. 77) contains the following statement: *It is ordinarie thing to drinke it (juice of mandragora) . . . before the cutting cauterizing, pricking or launcing of any member, to take away the sence and feeling of such extreme cures. And sufficient it is in some bodies to cast them into a sleep with the smell of Mandrage, against the time of such chirurgerie.*

In the writings of Pedacius Dioscorides is to be found the following description of the use of mandrake:

> *But of ye male (mandragora), and white which some have called Norion, ye leaves are greater, white, broad, smooth as of the beet, and ye apples twice as big, drawing to saffron in ye colour, sweet smelling with a certain strongness which also ye shepherds eating are in a manner made asleep . . . . And some do seeth the roots in wine to thirds, & straining it set it up. Using a Cyathus of it for such as cannot sleep, or are grievously pained, & upon whom being cut, or cauterized they wish to make a not-feeling pain . . . . Ye wine of ye bark of ye root is prepared without seething but you must cast in 3 pounds into a Metreta of sweet wine, & that there be given of it 3 Cyathi to such as shall be cut, or cauterized, as is foresaid. For they do not apprehend the pain, because they are overborn with dead sleep, but the apples being smelled to, or eaten are soporiferous, & ye juice that is of them.*

Dioscorides was a Greek surgeon in Nero's army, whose medical botany writings serve as an authoritative source for the First Century A.D. Until the great medical advances that were made in the 16th and 17th century, the works of Dioscorides were the primary foundation upon which the materia medica of western countries was based. It is impossible to overstate the influence which his work *De materia medica* had upon the physicians of the Middle Ages and Renaissance. Not only because it was the source for almost all botanical knowledge for a millenium and a half, but also because of the beauty of the manuscripts into which it was variously translated, Dioscorides' contribution is one of the classics of medical literature, and, in fact, of the field of Art History as well. In two places in his text, in addition to the above, Dioscorides recommends that mandrake is to be used in surgical operations or in cauterizations. Although it has been traditional to credit coining of the word *anesthesia* to Oliver Wendell Holmes, it was actually Dioscorides who first used it. The word was revived by Quistorp in 1719, and was used by John Elliotson and others acquainted with mesmerism in the 19th century, before Holmes finally made it stick by suggesting its use to William T. G. Morton in 1846.

It is mandragora which is the first anesthetic agent referred to in English, this by William Bullein, in 1562.

HYOSCYAMUS, or HENBANE

Henbane or *Hyoscyamus niger* is another plant the tranquillizing or anesthetic properties of which are due to its being a source of belladonna alkaloid. Although either the leaves or the seed were the part from which the drug was derived, the seed seems to have been preferred. Hyoscyamus was recognized as a very dangerous drug, and was, in fact, often used to kill dogs and mice. Dioscorides describes a method of burning the hyoscyamus under a tree, resulting in narcotized birds falling to the ground, whereupon those which had not been killed were easily caught and revived by instilling vinegar into their nostrils.

ALCOHOL and OTHERS

A record of the use of various alcoholic potions to induce anesthesia is to be found in Dioscorides; for example, a dose of two ounces of heavy wine was recommended by him to intoxicate patients about to be cut for stone or cauterized. When the use of amputation and other surgical procedures became more prevalent in the 16th and 17th centuries, the drunken state was a modality frequently used to induce senselessness or decreased awareness.

In addition to its being an ingredient of beer, the resinous and aromatic constituents of the hop plant (*Humulus lupulus*) have long been recognized to have sleep-producing properties. Prior to modern times the use of a hop-stuffed pillow was a popular device to treat insomnia.

The juice from the stem of the wild mature lettuce (*Lactuca silvestris*) was also known as an effective soporific, although a very mild one, being used primarily with other drugs. Another common sleep producer was mulberry (*Moren*), which was well known for centuries.

But it was upon the poppy, mandragora and hyoscyamus that physicians of Greek times and their successors in the Middle Ages and Renaissance relied primarily as narcotic agents. The word narcotic itself is, of course, derived from *narke,* the Greek word for "stupor," as the word anodyne comes from *nodynia*, "ease from pain." Thus, the Greeks left their methods and their terminology as indelibly stamped upon this area of pharmacology as they did upon so many others, until 18th and 19th century chemical discoveries made dependable and safe anesthesia a reality.

The Middle Ages and Renaissance

The Medieval mind was immersed in theology and devoted to rational thinking as its means of discovering truth. Solemn pronouncements based upon logic and pious reasoning were the outcome of an intellectual system that had little use for observation or experiment. Thus it was that the medicine of Galen (131-201 A.D.), depending as it did upon the concept of an infinitely wise Creator, remained the prevailing influence for more than a thousand years. Not only was Galen not an experimentalist and an observer—unfortunately, so inclined was he to see a divine logic in all of life that he tended to draw sweeping teleological conclusions from inadequate or sometimes erroneous evidence. Those Galenic conclusions dominated the mind of the Medieval physician.

No wonder, then, that the potions described by the peri-Galenic writers found their way, virtually unchanged, into the armamentarium of the physicians of the Middle Ages. Whether individually or in combination, there are references to their applicability throughout the writings of this period. The most popular method of inducing narcosis was the so-called soporific sponge, *spongia somnifera.* Historians have found descriptions of it in manuscripts dating to the 9th century. Nicholas of Salerno described its ingredients in the 12th century as opium, hyoscyamine, mulberry juice, lettuce seed, hemlock, mandrake, and ivy. A fresh sea-sponge was to be soaked in the mixture and allowed to dry "in the sun during the dog-days until all the liquid is consumed." When required for use, the concoction was to be reconstituted by dipping the sponge in water. Because the medieval manuscripts recommended applying the sponge to the subject's nostrils, it has been thought that this was meant to be a form of inhalation anesthesia , but there is good evidence that the potion was usually administered as a drink. Reversal of the narcotizing effect was to be attained with the juice of fennel-root or with vinegar.

References to soporific draughts are to be found in the literature of the later Middle Ages and Renaissance. Thus, in one of the tales told in Boccaccio's *Decameron,* a gangrenous leg is operated upon under the influence of such a potion. *The Tragicall Historye of Romeus and Juliet,* written in 1562 by Arthur Brooke, contains the description by Friar Laurence to Juliet of a certain potion which,

> Long since I did finde out,/and yet the way I know,
> Of certain rootes, and savory herbes/to make a kind of dowe,
> Which baked hard, and bet/into a powder fine,
> And drunk with conuite water, or/with any kynd of wine,
> It doth in halfe an howre/astonne the taker so,
> And mastreth all his sences, that/he feeleth weale nor woe:
> And so it burieth vp/the sprite and liuing breath,
> That even the skilfull leche would say,/that he is slayne by death.

Certainly, this poem was a source for Shakespeare in writing Romeo and Juliet. In Act IV, scene 1 of that play the Bard describes the result of a drink of "this distilling liquor," in terms so accurate that it is hard to believe that he had not personally witnessed its effects, or at least heard a first-hand account. Marlowe, Middleton, and Donne are other English writers in whose works can be found references to the opiates of the time.

As in all other areas of scientific thought, the Middle Ages were indeed the dark ages for any advances in the pharmacology of anesthesia. In addition to all of the well known reasons for the intellectual stagnation of the period there were two specific factors that militated against improvements in methods of narcosis. The first was, of course, the theological doctrine that pain serves God's purpose and therefore must not be alleviated; this is a concept that was to prove particularly significant during James Simpson's campaign to establish obstetrical anesthesia some centuries later. The second factor was a simple ignorance of dosages, strengths, and even of the active ingredients in the botanicals, because of which it was impossible to standardize results. The soporifics were accordingly regarded, and rightly so, as highly dangerous. Although they had been championed by surgeons as eminent as Guy de Chauliac of Avignon (1300-1368) and Hans von Gersdorff of Strassburg (16th century), the soporific sponges and similar draughts began to disappear from use, so that by the 17th century they were largely a thing of the past. One of the last English literary references to a narcotic mixture occurs in Act IV of Thomas Middleton's tragedy, *Women Beware Women* (1657):

> I'll imitate the pities of old surgeons
> To this lost limb, who, ere they show their art.
> Cast one asleep, then cut the diseased part.

(to be continued)

Transportation Expense Deductions

ARNOLD J. STREICH, JD

The Internal Revenue Service permits you to deduct transportation expense for your business or profession even though you are not away from home. Transportation expenses include such items as air, train, bus, and cab fares, and the expenses of driving and maintaining your car. Costs of traveling between your *home* (residence) and usual place of business within the area of your *tax home* (principal place of work or employment) are nondeductible commuting expenses under §262 of the Internal Revenue Code. (Tax Guide for Small Business, IRS Publication 334.)

Physicians' Automobiles

Although physicians have frequently litigated the issue as to the deductibility of their automobile expenses, the basic principles were developed in suits brought by nonphysicians. They then were applied across the board to all taxpayers, regardless of the type of work engaged in. The courts have generally supported the Internal Revenue Service in this regard. Also, the courts and the IRS are in agreement that a physician who uses his personal automobile in his practice cannot deduct all of his operating expenses.

The discussion which follows is intended to provide better insight into frequently unpopular IRS and court decisions.

"Tax Home"

The principle that "tax home" is a taxpayer's principal place of business was established by the United States Supreme Court in a 1946 decision which held that transportation costs from such "home" to taxpayer's residence are not deductible *(Commissioner v. Flowers,* 326 U.S. 465, 1946). The IRS has generally defined a taxpayer's "tax home" for purposes of the deduction for reasonable travel and lodging expenses as his *principal* place of business, employment station or post of duty, regardless of where he maintains his personal residence. (IRS [Private] Letter Ruling No. 8121050, February 26, 1981.)

Nature of a Taxpayer's Business or Profession

Nature of a Taxpayer's Business or Profession in the area of personal v. business transportation and travel expenses, no exceptions have been made on the basis of the nature of a taxpayer's business or profession. Nor is the "necessity" of transportation, whether it involves long or short distances from a taxpayer's residence to his place of work a decisive factor. When transportation expenses are incurred by a taxpayer in making daily round trips, requiring no sleep or rest between the taxpayer's residence and place of work, the travel expense deduction in §162(a) of the Internal Revenue Code is inapplicable. *(U.S. v. Correll,* 389 U.S. 299, 1967)

Distance Traveled

Deductibility of commuting costs as ordinary and necessary business expenses is controlled by *U.S. v. Tauferner,* (CA-10, 407 F.2d 243, 1969, *cert. denied* 396 U.S. 824, 1969), according to the Tenth Circuit's decision in *G.D. Pilcher v. Commissioner* (CA-10, 651 F.2d 717, 1981), where a pipefitter employed on a construction project who had to travel from his residence in Salt Lake City to Great Salt Lake—a roundtrip of 67 miles—was held not entitled to deduct travel expenses to and from the jobsite.

Controlling Decisions

The Tenth Circuit's decision in *Tauferner* (supra.) and the U.S. Supreme Court's decision in *Correll* (supra.) are the authorities most frequently cited for the principles applicable to cases in which the taxpayer seeks to deduct costs of travel and transportation as business expenses. In *W.B. Turner v. Commissioner* (56 T.C.27, 1971), a consultant engineer residing in New York City who daily traveled considerable distances by automobile to work outside the City and home was held by the Tax Court to be a commuter; therefore, his transportation expenses were not deductible under §162(a) of the Internal Revenue Code. Citing *Correll* (supra.) and *Tauferner* (supra.) the court said: Commuting is commuting, regardless of the work engaged in, the distance traveled, or the mode of transportation used. Our path was charted in *United States v. Tauferner,* supra."

ARNOLD J. STREICH, JD, at the time of this writing, served as Assistant General Counsel of the American Medical Association. This is one of a series of papers prepared by the AMA for publication in state medical journals on subjects of interest to practicing physicians. They will appear in no other publications.

In the *Tauferner* case, the taxpayer deducted the cost of his daily transportation between his residence in Brigham City, Utah, and a chemical plant where he worked as a contracts administrator. He traveled back and forth usually by public transportation using his own car only when he had to travel outside the bus schedule. The roundtrip covered 27 miles. Tauferner deducted the costs as ordinary and necessary business expenses under §162(a) of the Code. The IRS denied the deduction on the ground that his travel expenses were no different than that of any commuter.

What Facts Are Determinative

As the Supreme Court said in *Correll,* "any rule in this area must make some arbitrary distinctions. The nature of the work engaged in, the distance traveled, the mode of transportation, the degree of necessity appear to be unsatisfactory guides with any degree of consistency and certainty. The basic unmodified fact of whether the taxpayer is going to the place where he begins his work or is returning from the place where he ceases work should be determinative. Such travels are expenses within §262 as personal, living or family expenses whether in an urban, suburban, or rural setting. They are not business expenses under §162(a)."

In-Between Transportation

Of course, work patterns differ. One person may travel from his residence to his place of employment and remain there. At the end of his workday, he will return to his residence. Another may require travel from residence to principal place of employment, from there to other work sites, return to his principal jobsite and then home at the end of the workday. Sometimes, this place to place travel will vary, with the first stop in the morning at one of the in-between jobsites, and the last stop before returning home at either another in-between jobsite or the principal place of employment.

The principal question is whether the claimed deductions for transportation are ordinary and necessary business expenses within the meaning of §162(a) of the Internal Revenue Code. That is a question of fact. The determinative question involving ordinary and necessary business expenses when an automobile is used is whether the taxpayer is going to the place where he begins work and is returning to the place where he ceases work.

Travel between one's residence and regular place of employment is a non-deductible personal expense. "In-between" travel—principal place of employment to another jobsite—is deductible business transportation. Return to the principal place of employment from the other jobsite is similarly deductible. However, travel to the first place of employment or from the last place of employment for the day, whether such place is the "tax home" or an "in-between" jobsite, is nondeductible commuting. *(Sanders v. Commissioner,* CA-9, 139 F.2d 296, 1971)

Extra Duty Travel

A taxpayer employed as a staff physician at a VA hospital made 160 roundtrips by automobile from his residence to the hospital to fulfill his responsibility for "extra-duty patient care" performed outside his regular duty hours during a taxable year. Each roundtrip was 36 miles. The doctor computed the cost of those trips at $576 and it was this amount that he deducted as business transportation expenses.

In denying this extra-duty deduction, the Tax Court, citing its earlier decision in *M.G. Sheldon* (50 T.C.24, 1968), said: "Although commuting expenses are incurred in order to reach one's place of employment, they are treated as nonbusiness expenses since their amount depends upon the place one chooses to reside—a choice which results from personal and family considerations. This reasoning applies equally to the expense of commuting for regular duty or for extra duty." *(J.M. O'Hare,* 54 T.C.874, 1970.)

On Emergency Call

In *M.G. Sheldon,* supra; the taxpayer, a physician who specialized in anesthesiology, was a fulltime employee at a hospital. Her usual working hours, Monday through Friday, were 8 AM to 4:30 PM. In addition, she was on call for 24 hours every other weekday and on call for 48 hours every other weekend. She had no outside medical practice.

The anesthesiologist contended that she was entitled to deduct at least 60% of her automobile expenses. She believed that use of her automobile in response to emergency calls received at home was essential to performance in her employment. Furthermore, it was not feasible to use public transportation to the hospital. The Tax Court held that emergency calls were nondeductible commuting expenses.

Emergency Calls at Social Engagements

A federal district court *(Dr. Phillip Cenac v. U.S.,* D.C. La., 67-2 USTC ¶9576, 1966) stated that even where a physician is on emergency call and he takes his business automobile to a social function for that specific reason, some part, at least, of that transportation use is a personal one. "These uses . . . going to and from work, going home for lunch, going to social engagements, even when the doctor is on call, are similar to personal uses that everyone has in his personal life, and they are not considered under the law as business uses."

Some Departures from the Rules

A few courts, however, have allowed a deduction for second hospital trips from home, trips to patients' homes from home after the workday, and emergency visits to the hospital for critically ill patients, *(Karl Wolf v. U.S.,* D.C., MO., 64-1 USTC ¶92111). In *J.R. Bovington* (DC, Mont., CV7733H, December 27, 1977), the federal district court allowed a physician to deduct automobile expenses which appeared to include allowances for emergency calls and for trips to hospitals and patients subsequent to the first trip from home. The physician-taxpayer, who lived in Helena, Montana had no set pattern to his daily work schedule. He sometimes started his workday by traveling from his residence either to the hospital, to a nursing home, or to any other place involving his practice. He also traveled *between* the various places where he practiced medicine. Also, he was on call at all times of the day and night with respect to patient care.

Although the physician did not keep a record of the actual miles involved in the use of his automobile for his practice and those used for private or other purposes, the court accepted the yearly mileage figure claimed by the doctor as attributable to use in his practice. In this connection, the computation was made on the basis of a claimed 15,000 miles per year at 12¢ per mile, 46 work weeks during the taxable year, 5 work days each week, less 4 miles round trip between the doctor's office and his home. This resulted in a refund allowed by the Court as follows:

15,000 miles @ .12¢	$1,800.00
Less:	
46 weeks x 20 (5 days per week x 4 miles per day) x .12¢ per mile	106.40
Deductible under I.R.C. §162(a)	$1,693.60

Given the trip patterns each day and the fact that the physician was on call at all times during the day and night, one might assume that the physician probably had a number of second from home to hospital trips during the taxable year. If that in fact was the case, then the federal court might not have taken into account the prevailing rule that would have treated these second trips as commuting.

Change in Law and Regulations

In 1976 the Internal Revenue Service issued a ruling (Rev. Rul. 76-453, 1976-2 CB 86) that reconsidered earlier rulings in light of the U.S. Supreme Court's decision in *Correll* (supra), the tax court's decision in *Turner* (supra) and CA-10's decision in *Tauferner* (supra). The ruling provided examples of its latest position. One example in Rev. Rul. 76-453 incorporates facts similar to the "no set pattern" travel in *Bovington* except that the taxpayer's principal place of work is located at his residence. Where these were the facts, the IRS said: "On days that Roe drives to one or more other places of work, the entire amount of transportation expenses is deductible." Before the Ruling could become operative, however, it was withdrawn pursuant to Public Law 95-427 (as amended by Public Law 96-167) which provided that, with respect to transportation costs paid or incurred after 1976 and before June 1, 1981, the revenue ruling in question (and any other regulation, ruling or discussion reaching the same or similar result) was not to be applied to the transportation expenses to which the ruling applied. Instead, such costs were to be determined with full regard to the rules in effect before Revenue Ruling 76-453. It was intended that the provision would allow Congress time to study this matter prior to the effective date of any changes made by new regulations or rules issued by the IRS.

To date Congress has not enacted new law in this area. Since the deadline set by Congress (May 31, 1981) has passed, the IRS is now free to lift its supension of Rev. Rul. 76-453. No action has been reported by IRS, so it would appear that the ruling continues to be indefinitely suspended.

In order to stay current it is important that you consult with your tax advisor.

It's about time you had a real professional assist you in attaining your personal, practice and retirement investment goals.

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Essentials and Guidelines for Accreditation of Intrastate Sponsors of Continuing Medical Education

CSMS COMMITTEE ON CONTINUING MEDICAL EDUCATION

BACKGROUND—The original *Essentials for the Accreditation of Institutions and Organizations Offering Continuing Medical Education* was adopted by the American Medical Association in 1970, and served as the basis for the accreditation by AMA of national providers of CME, and by state medical societies of intrastate providers of CME. The original *AMA Essentials* also were used by the Liaison Committee on CME (LCCME), which succeeded the AMA as national CME accrediting body in 1977, and until October, 1982, by the Accreditation Council for CME (ACCME), which is currently the national CME accrediting body. As one of its first tasks, the ACCME has rewritten the *Essentials,* with the participation and assistance of the AMA's Advisory Committee on CME, (chaired by former CSMS President Jerome K. Freedman of New Haven) and the CME Committees of the state medical societies. ACCME has also added *Guidelines,* to explain and illustrate various methods of compliance. These new *Essentials and Guidelines* were then approved by the AMA and other component bodies of ACCME, and finally adopted on October 29, 1982.

Besides its function as accrediting body for national CME providers, the ACCME has also established criteria for the continuing recognition of state medical societies as accrediting agencies for intrastate sponsors, the first of which is that each state society adopt *Essentials for Accreditation* that are consistent with the ACCME *Essentials.* The Connecticut State Medical Society's Committee on CME, chaired by Marvin Garrell, M.D., of Bridgeport, found that the new *ACCME Essentials* varied little in substance from the previous LCCME and AMA Essentials; they are, however, more clearly organized and more specific. Therefore the Committee adopted them as the *CSMS Essentials* in July of 1983, and revised its own presurvey questionnaire accordingly. Both these documents were promulgated to the Directors of Medical Education in all the CSMS-accredited hospitals and organizations providing CME, and are now in effect as the basis for future CSMS accreditation and renewal actions.

CSMS itself is tentatively scheduled for a site visit from ACCME for continuing recognition as an accrediting agency for intrastate CME sponsors in the coming year, and our Committee and staff are currently reviewing standards and procedures to assure compliance with ACCME criteria.

Robert J. Brunell, CME Committee Staff

Guidelines to the Essentials have been developed in order to explain in greater detail the meaning and application of the Essentials and to provide information to sponsors on how they can comply with the Essentials. These guidelines are not intended to limit the manner in which sponsors may meet the requirements for accreditation. Examples cited are intended only for clarification, not as indications of preferences or priorities. The Guidelines follow the organizational structure of the Essentials. The text of the Introduction and each Essential with its Explanation and Rationale is given first, followed by the corresponding guidelines.

Introduction

The Connecticut State Medical Society's Committee on Continuing Medical Education conducts a voluntary accreditation program for Connecticut institutions and organizations providing continuing medical education (CME). By evaluating and granting recognition to an institution or organization whose CME program substantially complies with the standards or "Essentials," the CSMS seeks to improve the quality of CME and to assist physicians in identifying CME programs which meet these standards.

The CSMS recognizes that the professional responsibility of physicians requires continuous learning throughout their careers, appropriate to the individual physician's needs. The CSMS also recognizes that physicians are responsible for choosing their own CME and evaluating their own learning achievement. The "Essentials," therefore, are designed to encourage and foster

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BRIEF SUMMARY
PROCARDIA® (nifedipine) **CAPSULES** For Oral Use

INDICATIONS AND USAGE: I. Vasospastic Angina: PROCARDIA (nifedipine) is indicated for the management of vasospastic angina confirmed by any of the following criteria: 1) classical pattern of angina at rest accompanied by ST segment elevation, 2) angina or coronary artery spasm provoked by ergonovine, or 3) angiographically demonstrated coronary artery spasm. In those patients who have had angiography, the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina, provided that the above criteria are satisfied. PROCARDIA may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed, e.g., where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm, or when angina is refractory to nitrates and/or adequate doses of beta blockers.

II. Chronic Stable Angina (Classical Effort-Associated Angina): PROCARDIA is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents.

In chronic stable angina (effort-associated angina) PROGARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in those patients are incomplete.

Controlled studies in small numbers of patients suggest concomitant use of PROCARDIA and beta blocking agents may be beneficial in patients with chronic stable angina, but available information is not sufficient to predict with confidence the effects of concurrent treatment, especially in patients with compromised left ventricular function or cardiac conduction abnormalities. When introducing such concomitant therapy, care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs. (See Warnings.)

CONTRAINDICATIONS: Known hypersensitivity reaction to PROCARDIA.

WARNINGS: Excessive Hypotension: Although in most patients, the hypotensive effect of PROCARDIA is modest and well tolerated, occasional patients have had excessive and poorly tolerated hypotension. These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment, and may be more likely in patients on concomitant beta blockers.

Severe hypotension and/or increased fluid volume requirements have been reported in patients receiving PROCARDIA together with a beta blocking agent who underwent coronary artery bypass surgery using high dose fentanyl anesthesia. The interaction with high dose fentanyl appears to be due to the combination of PROCARDIA and a beta blocker, but the possibility that it may occur with PROCARDIA alone, with low doses of fentanyl, in other surgical procedures, or with other narcotic analgesics cannot be ruled out. In PROCARDIA treated patients where surgery using high dose fentanyl anesthesia is contemplated, the physician should be aware of these potential problems and, if the patient's condition permits, sufficient time (at least 36 hours) should be allowed for PROCARDIA to be washed out of the body prior to surgery.

Increased Angina: Occasional patients have developed well documented increased frequency, duration or severity of angina on starting PROCARDIA or at the time of dosage increases. The mechanism of this response is not established but could result from decreased coronary perfusion associated with decreased diastolic pressure with increased heart rate, or from increased demand resulting from increased heart rate alone.

Beta Blocker Withdrawal: Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina, probably related to increased sensitivity to catecholamines. Initiation of PROCARDIA treatment will not prevent this occurrence and might be expected to exacerbate it by provoking reflex catecholamine release. There have been occasional reports of increased angina in a setting of beta blocker withdrawal and PROCARDIA initiation. It is important to taper beta blockers if possible, rather than stopping them abruptly before beginning PROCARDIA.

Congestive Heart Failure: Rarely, patients, usually receiving a beta blocker, have developed heart failure after beginning PROCARDIA. Patients with tight aortic stenosis may be at greater risk for such an event.

PRECAUTIONS: General: Hypotension: Because PROCARDIA decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of PROCARDIA is suggested. Close observation is especially recommended for patients already taking medications that are known to lower blood pressure. (See Warnings.)

Peripheral edema: Mild to moderate peripheral edema, typically associated with arterial vasodilation and not due to left ventricular dysfunction, occurs in about one in ten patients treated with PROCARDIA. This edema occurs primarily in the lower extremities and usually responds to diuretic therapy. With patients whose angina is complicated by congestive heart failure, care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

Drug interactions: Beta-adrenergic blocking agents: (See Indications and Warnings.) Experience in over 1400 patients in a non-comparative clinical trial has shown that concomitant administration of PROCARDIA and beta-blocking agents is usually well tolerated, but there have been occasional literature reports suggesting that the combination may increase the likelihood of congestive heart failure, severe hypotension or exacerbation of angina.

Long-acting nitrates: PROCARDIA may be safely co-administered with nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

Digitalis: Administration of PROCARDIA with digoxin increased digoxin levels in nine of twelve normal volunteers. The average increase was 45%. Another investigator found no increase in digoxin levels in thirteen patients with coronary artery disease. In an uncontrolled study of over two hundred patients with congestive heart failure during which digoxin blood levels were not measured, digitalis toxicity was not observed. Since there have been isolated reports of patients with elevated digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing PROCARDIA to avoid possible over- or under-digitalization.

Carcinogenesis, mutagenesis, impairment of fertility: When given to rats prior to mating, nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose.

Pregnancy: Category C. Please see full prescribing information with reference to teratogenicity in rats, embryotoxicity in rats, mice and rabbits, and abnormalities in monkeys.

ADVERSE REACTIONS: The most common adverse events include dizziness or light-headedness, peripheral edema, nausea, weakness, headache and flushing each occurring in about 10% of patients, transient hypotension in about 5%, palpitation in about 2% and syncope in about 0.5%. Syncopal episodes did not recur with reduction in the dose of PROCARDIA or concomitant antianginal medication. Additionally, the following have been reported: muscle cramps, nervousness, dyspnea, nasal and chest congestion, diarrhea, constipation, inflammation, joint stiffness, shakiness, sleep disturbances, blurred vision, difficulties in balance, dermatitis, pruritus, urticaria, fever, sweating, chills, and sexual difficulties. Very rarely, introduction of PROCARDIA therapy was associated with an increase in anginal pain, possibly due to associated hypotension.

In addition, more serious adverse events were observed, not readily distinguishable from the natural history of the disease in these patients. It remains possible, however, that some or many of these events were drug related. Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2%. Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0.5% of patients.

Laboratory Tests: Rare, mild to moderate, transient elevations of enzymes such as alkaline phosphatase, CPK, LDH, SGOT, and SGPT have been noted, and a single incident of significantly elevated transaminases and alkaline phosphatase was seen in a patient with a history of gall bladder disease after about eleven months of nifedipine therapy. The relationship to PROCARDIA therapy is uncertain. These laboratory abnormalities have rarely been associated with clinical symptoms. Cholestasis, possibly due to PROCARDIA therapy, has been reported twice in the extensive world literature.

HOW SUPPLIED: Each orange, soft gelatin PROCARDIA CAPSULE contains 10 mg of nifedipine PROCARDIA CAPSULES are supplied in bottles of 100 (NDC 0069-2600-66), 300 (NDC 0069-2600-72), and unit dose (10x10) (NDC 0069-2600-41). The capsules should be protected from light and moisture and stored at controlled room temperature 59° to 77°F (15° to 25°C) in the manufacturer's original container.

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self-directed physician participation in CME, in which physicians assume full responsibility for the choice of their CME activities in accordance with their perceived needs, individual preferences of learning methods, and practice settings. Sponsors should take into consideration the needs and interests of potential physician participants in planning their CME activities, and encourage these physicians to assume active roles in the planning process.

In the "Essentials" the CSMS has identified certain elements of organization, structure, and method which appear to contribute significantly to the development of continuing medical education. They are presented here in the *Essentials for Accreditation of Sponsors of Continuing Medical Education* (Essentials).

The "Essentials" are made up of those requirements which a sponsor must substantially meet for accreditation. An Explanation and Rationale are also provided. The "Essentials" should prove valuable as a resource for physicians planning their own CME and for sponsors designing CME programs.

The CSMS will review the "Essentials" on a continuing basis and will modify them as knowledge and experience dictate.

It is important to note that the CSMS does not accredit individual CME activities, but institutions and organizations for their overall program of CME. The overall program consists, at least in part, of one or more educational activities, developed according to these "Essentials," which provide direct teacher-participant interaction.

The following definitions will be useful in reviewing the "Essentials" and in gaining an understanding of the accreditation process:

Continuing Medical Education (CME): Continuing Medical Education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

This broad definition of CME recognizes that all continuing educational activities which assist physicians in carrying out their professional responsibilities more effectively and efficiently are CME. A course in management would be appropriate CME for physicians responsible for managing a health care facility; a course in educational methodology would be appropriate CME for physicians teaching in a medical school; a course in practice management would be appropriate for practitioners interested in providing better service to patients.

Not all continuing educational activities which physicians may engage in, however, are CME. Physicians may participate in worthwhile continuing educational activities which are not related directly to their professional work, and these activities are not CME. Continuing educational activities which respond to a physician's nonprofessional educational need or interest, such as personal financial planning, and appreciation of literature or music, are not CME.

Purpose of CME Accreditation: To assure physicians and the public that CME activities meet accepted standards of education.

CME Accreditation: The recognition accorded eligible institutions and organizations which meet the "Essentials."

Program of CME: The overall CME program of a sponsor consists of one or more educational activities consistent with the "Essentials."

CME Activity: A coherent educational offering which is based upon defined needs, and explicit objectives, educational content, and methods.

A Sponsor: An institution or organization assuming responsibility for CME.

A Participant: A physician engaged in CME.

The Essentials: The document which provides information regarding CSMS accreditation and the standards which must substantially be met for a sponsor of CME to be accredited.

Program of CME. Accreditation is granted on the basis of the sponsor's demonstrated ability to plan and implement CME activities in accordance with the Essentials. The sponsor's overall program may include occasional CME activities that do not fully meet the standards for needs assessment, well-defined objectives, curricular design, and evaluation. These activities are part of the accredited sponsor's overall CME program as long as the sponsor exercises responsibility for these activities through its recognized CME administrative unit. The organization should identify those CME activities within its overall program which meet the Essentials, e.g. by designating them as AMA Category I CME.

These CSMS Essentials and Guidelines are consistent with the Essentials and Guidelines of the national Accreditation Council for Continuing Medical Education (ACCME), the accrediting authority for national CME sponsors. ACCME also sets criteria for the continuing recognition of state medical societies as the accrediting bodies for intrastate CME sponsors.

Designation of CME credit relates to the requirements of credentialing agencies, certificate programs, or membership qualifications of various societies, and the accredited sponsor is responsible to these agencies, programs, and societies in the matter of designation of credits and verification of physician attendance. The designation of credit for specific CME activities is *not* within the purview of ACCME or of the state medical associations as accrediting bodies. (For information concerning Designation of AMA Category I CME credit, see pages 13 and 18 of the accompanying 1983 Information Booklet for the American Medical Association Physician's Recognition Award.)

THE ESSENTIALS

The following seven ESSENTIALS comprise the criteria, or standards, by which eligible sponsors of continuing medical education are evaluated in order to determine their qualification for accreditation by the CSMS.

ESSENTIAL #1

THE SPONSOR SHALL HAVE A WRITTEN STATEMENT OF ITS CONTINUING MEDICAL EDUCATION MISSION, FORMALLY APPROVED BY ITS GOVERNING BODY. THE MISSION STATEMENT SHALL:

1. *Describe the goals of the overall CME program in a concise manner.*
2. *Indicate the scope of the CME effort.*
3. *Outline the characteristics of the potential participants.*
4. *Describe the general types of activities and services provided.*

Explanation and Rationale

In order to provide quality CME, it is essential to have a written mission statement which has been agreed upon by the Governing Body. This statement outlines what is expected of the CME organization and serves as a basis for a more objective evaluation of its ability to meet its mission. Without such a document, there may be misunderstandings as to the scope and nature of the CME activities undertaken. With an agreed-upon mission statement, the CME organization can more easily seek needed support from its Governing Body to accomplish its required functions.

Guidelines

The mission statement identifies what the sponsor desires to accomplish through its overall program of CME. It describes the educational goals of the overall program in terms of content or expected learning, the physicians for whom the educational program is intended, and the general kinds of educational activities and services which will be used to accomplish these goals. It is desirable to relate the educational goals of the overall program, as found in the CME mission statement, to the primary purpose or mission of the sponsor as an institution or organization.

The mission statement should serve as an effective point of reference for individual CME programming and evaluation of the overall program. The mission statement should be periodically reviewed in the light of experience and revised if necessary.

ESSENTIAL #2

THE SPONSOR SHALL HAVE ESTABLISHED PROCEDURES FOR IDENTIFYING AND ANALYZING CONTINUING MEDICAL EDUCATIONAL NEEDS AND INTERESTS OF PROSPECTIVE PARTICIPANTS. THE SPONSOR SHALL:

1. *Document the processes used to identify CME needs, including data sources which go beyond the sponsor's own perception of need.*
2. *State the overall needs identified by the above processes and indicate how this assessment is used in planning educational activities.*

Explanation and Rationale

Identification and analysis of CME needs (needs assessment) provides the basis for formulating educational objectives and planning educational activities. Needs assessment results in a statement specifying instructional intent and/or expected learning outcomes. Needs may be perceived and/or identified by both the physician participant and the sponsor. Setting priorities for identified needs will assist the sponsor in planning educational activities.

Guidelines

Educational needs and interests refer to any knowledge, skill, or attitude that physicians either should or wish to acquire, develop or reinforce. Participants should be treated as professionals with respect for their knowledge, experience, and self-motivation. Therefore, a goal for every CME activity should be to increase, or at least to maintain, the participants' desire to continue their medical education. This important goal of CME should be kept in mind when designing the activity, i.e., choosing the educational methods, selecting instructors, and determining methods of evaluation. The way that educational subjects are presented, as well as the instructor's manner with participants, influence the motivation of physicians not only to learn during the activity but to continue learning after the activity is completed.

The sponsor may use a wide variety of procedures to identify needs, such as a sample survey interview of prospective participants, analysis of self-assessment examination results, epidemiological data, patient care audit, or a search of current literature or consensus of experts in a particular field. The sponsor should attempt to weigh the relative importance of the needs identified, and determine the planning of CME activities and use of resources with these priorities in mind.

The term "need" usually connotes some degree of necessity or obligation. The necessity or obligation may arise from a physician's sense of responsibility to maintain or improve personal professional activities. This necessity or obligation may also arise from external requirements of some organization or agency such as a licensure board, certifying agency, specialty society, or hospital staff.

The term "interest" connotes an educational want or desire. Physicians may desire some knowledge, skill, or attitude not perceived as necessarily directly applicable to their medical practice. For instance, a physician may desire to learn more about a particular development in his medical research yet realize that this knowledge may not be directly applicable in his medical practice. CME based on interests has a place in the continuing education of physicians. Interests, however, should not be the only or primary criterion of choice for physicians.

An educational need may be "real" yet exist independent of the awareness of the physician. A real need becomes a "perceived" need when the physician is aware of it. Unless physicians perceive an educational need as their own, any CME activity based on that need is unlikely to be successful in effecting real learning or in attracting participants. If the educational need is real, but unperceived, physicians may need assistance recognizing that need.

An *educational need* is not the same as a performance need. Needs identified by quality assurance programs, for instance, do not necessarily indicate a lack of knowledge or skill. Sponsors may wish to analyze performance needs to determine whether there is, in fact, a need for physician learning and not assume that performance deficiencies can be successfully addressed through educational activities.

ESSENTIAL #3

THE SPONSOR SHALL HAVE EXPLICIT OBJECTIVES FOR EACH CME ACTIVITY. THE SPONSOR SHALL:

1. *State the educational need(s) which the individual activity addresses.*
2. *Indicate the physicians for whom the activity is designed.*
3. *List any special background requirements of the prospective participants.*
4. *Highlight the instructional content and/or expected learning outcomes in terms of knowledge, skills, and/or attitudes.*
5. *Make these objectives known to prospective participants.*

Explanation and Rationale

Clearly stated objectives provide prospective participants with a realistic understanding of the nature and purposes of the CME activity. This allows prospective participants to select educational activities which meet their needs. It also helps sponsors to target educational activities to meet explicit needs. A CME activity which takes place over a period of time, e.g., weekly grand rounds, may be covered by a single set of objectives.

Guidelines

The development of objectives serves three functions: 1) assisting sponsors in planning, designing and implementing educationally effective activities; 2) assisting sponsors in evaluating the quality of CME activities; and 3) assisting prospective participants in judging whether or not a CME activity meets their needs or interests. The adequacy of a sponsor's development of objectives depends on how well these objectives fulfill these three functions.

Explicit objectives means that the objectives are clear and of sufficient detail so that they are capable of fulfilling the three functions outlined above. Objectives need not be overly detailed.

These objectives should relate to the needs identified in Essential #2. Such needs might include updating existing medical knowledge or technical skills, the learning of new concepts or methods, or the sharing of new ideas and experiences to stimulate the development of knowledge or skills.

An objective that is properly conceived and clearly stated constitutes an important link in the educational chain. Good objectives are formulated from identified needs or interests and written in terms that facilitate evaluation. Clear objectives aid in judging the success of the CME activity.

In contrast to goals, which are general and long-range, objectives are specific, short-range, and more action-oriented. Objectives may be defined with respect to instructional content, levels of knowledge or performance, degrees of skill or technique, and changes in attitude or behavior relating to patient care that are the desired results of the CME activity.

Keeping one or more of the following questions in mind may help in developing good objectives: Will attainment of these objectives meet the identified needs? What will the participants be expected to know or be able to do as a result of the CME activity? How is the participant's attitude or behavior expected to change? How do these relate to patient care or other professional activities? Can attainment of the objectives be measured or evaluated?

The Essentials place great importance on the principle that physicians are responsible for choosing their own CME, in accordance with their perceived needs, preferred learning methods, and practice settings. In accordance with this principle, sponsors must make known to prospective participants the objectives of the activity, indicate the physicians for whom the activity is designed, list any special background requirements for effective participation, and state the educational methods that will be used. This information should appear on promotional materials and printed programs. Individual educational objectives need not be stated for each part or unit of an activity if the objectives are apparent or if they are summarized in the CME activity description.

Each CME activity should be described in terms of the broad or specific groups of physicians for whom it may have value. For example, a particular CME activity may be intended to bring a new medical concept to the attention of an entire specialty group or to a range of related specialty groups, or it might be a more limited concept intended for a subspecialty group.

A prospective CME participant should be informed as to the levels of skill or knowledge required for full participation in, and comprehension of, each CME activity. For instance, it may be suggested that each participant review a specific area of regional anatomy before participating in a CME activity in order to better comprehend the specific surgical procedure or diagnostic technique to be introduced or discussed. One might also be requested to review the broad classification of tumors of a specific area in preparation for a better understanding of the more detailed presentation of the management of tumors of this area.

When parts or units of a CME activity are integrally related to the entire activity, one set of objectives may be sufficient. This applies whether the parts or units of an activity are united in time (e.g., a three-day conference) or appear as distinct units over a period of time (e.g., grand rounds).

ESSENTIAL #4

THE SPONSOR SHALL DESIGN AND IMPLEMENT EDUCATIONAL ACTIVITIES CONSISTENT IN CONTENT AND METHOD WITH THE STATED OBJECTIVES. THE SPONSOR SHALL:

1. *Design and implement educational activities responsive to the characteristics of prospective participants, such as, knowledge levels, professional experience, and preferred learning styles.*
2. *Document use of systematic planning procedures.*
3. *Make educational content and methods know to prospective participants.*

Explanation and Rationale

After the identified needs have been translated into explicitly stated educational objectives it is important to design and implement educational activities in a way that facilitates meeting the objectives. The selection and organization of content, and decisions about educational formats, methods, media, and faculty should be based upon what seems most effective and efficient in meeting these objectives. These same elements pertain to sponsored CME activities which provide information and assistance to physicians engaged in self-directed learning.

Guidelines

The term "*sponsor*" is comprehensive, referring to the institution/organization accredited for its overall *CME program.* Implicit in the use of this term is the fact that a number of people with different responsibilities may be involved in the design and implementation of the CME activities that comprise the CME program. A group that is representative of the institutional/organizational membership (usually designated the "education committee") usually has responsibility for the operational aspects of the CME program.

Design and implementation of CME activities implies systematic *planning.* Planning of *any* CME activity, ranging from a one-hour conference to a multi-day symposium, involves a sequence of tasks, with each successive step depending upon completion of the previous one.

An initial step should be to review evaluation data from previous similar CME activities when available.

A major consideration is the *characteristics of prospective participants,* ie, for whom the CME activity is primarily intended/designed, viz., certain specialists or the entire medical staff. After identifying the "target," one should make preliminary assumptions regarding participants' current knowledge levels in the subject matter, past professional experiences, and types of learning methods appropriate for that group and subject.

A closely related task is *needs assessment,* (Essential #2) ie, "Why is this CME activity being held?" Whatever the method used to identify needs, the assessment should determine whether acquisition of information, knowledge or skill is the basic need, or whether a review/refresher, an update, or presentation of new concepts is required.

A next and important step is the development and statement of *objectives* for the CME activity (Essential #3). There should be a clear, concise statement of what the participants should learn and/or be able to do as a result of the CME activity. Such a statement, evolving from the previous planning activities, provides a useful focus for the participants and for the teachers. This can be especially valuable when there are many and varied CME activities available to the physician. For the teacher, it should determine preparation and selection of teaching methods.

Selection of *"faculty,"* i.e., the person(s) who will be invited to conduct the CME activity, is determined by several factors: foremost, the availability of competent and enthusiastic individuals; the level of expertise required; the extent of preparation necessary; and available resources. Good faculty can often be identified with one's own organization. External faculty should be selected to meet the defined objectives and not primarily for their charisma.

Effective planning requires that the format and educational methods be appropriate to the objectives. Sufficient time should be allocated for faculty and participants to accomplish the objectives. Optimal opportunity should be given to participants to be involved actively in implementation of the CME objectives.

Evaluation of the activity (Essential #5) is an integral part of the planning and should be incorporated into the design. Whether the activity is simple or complex, short or long, some form of evaluation should be planned. At a minimum, participants should provide feedback regarding achievement of the objectives, i.e., were CME needs met. Additionally, effectiveness of the educational method, the faculty, and other aspects of the activity can be critiqued. Evaluation completes the process cycle and should lead to refinements in planning for future CME activities.

Other tasks pertain more directly to implementation of CME objectives and include scheduling, arrangements for facilities, audiovisual equipment/services, preparation of educational materials, i.e., handouts, slides, transparencies, etc. Decisions regarding these aspects should be made in collaboration with, and under the guidance of, the person(s) responsible for the CME program.

The Essentials encourage and foster self-directed learning in the sense that physicians should be actively responsible for their own continuing medical education. Physicians are encouraged to identify their own educational needs and interests and to develop plans to meet these needs and interests. Effective planning for a self-designed educational program would include the elements of identification of need, development of educational objectives, choice of appropriate educational activities, and evaluation. The educational activities chosen may include a variety of forms, from reading to formally organized courses. A time schedule for completing the self-designed program is highly advisable.

Some physicians may desire assistance in developing self-designed educational programs. Consultation with those experienced in planning CME activities, experienced medical librarians, or physician specialists may be helpful. Sponsors may wish to offer assistance to physicians in developing "self-directed" individual CME programs. Sponsors who have the resources may desire to offer this assistance and are encouraged to do so.

Documentation of the systematic planning procedures is an integral part of an institutional/organizational CME program. Again, whether regularly-scheduled intra-institutional activities, periodic conferences, courses, seminars, symposia or workshops, it is useful to have a written record of education committee or other planning group meetings; correspondence relating to faculty, facility, financial arrangements, as indicated; needs assessment; objective-setting; evaluation. Such documentation need not be complicated or time-consuming, but should be sufficient for the particular CME activity. Patently, this information and related data are valuable in monitoring the overall program, ensuring continuity, planning future CME activities, and as evidence of fulfillment of requirements for continued accreditation.

Prospective participants should be informed in advance about the specific content and format for a CME activity, for several reasons: 1) it enables them to select CME content that is relevant to their needs and/or interests; 2) in locales where many CME offerings are available, advance information allows the physician to choose activities that are best suited to personal needs and time allocation; 3) when some preparation is desirable or required, this can be accomplished, thereby enhancing the extent and value of participation; 4) they will know the extent and type of participation expected of them; 5) in some respects, this information represents "truth in advertising." Physicians who are uninformed or misinformed will be disgruntled, with the result that they may not participate in future activities. Advance publicity reflects proper planning and conveys a favorable impression to the physician regarding the potential worth of the CME activity.

ESSENTIAL #5

THE SPONSOR SHALL EVALUATE THE EFFECTIVENESS OF ITS OVERALL CONTINUING MEDICAL EDUCATION PROGRAM AND COMPONENT ACTIVITIES AND USE THIS INFORMATION IN ITS CME PLANNING. THE SPONSOR SHALL:

1. *Periodically review the extent to which the sponsor's CME mission is being achieved by its educational activities.*
2. *Show that these evaluations assess:*
   a. *the extent to which educational objectives are being met;*
   b. *the quality of the instructional process;*
   c. *participants' perception of enhanced professional effectiveness;*
3. *Use evaluation methods which are appropriate and consistent in scope with the educational activity.*
4. *Demonstrate that evaluation data are used in planning future CME activities.*

Explanation and Rationale

The systematic gathering of evaluation data and their analysis, including evaluation of individual CME activities, is necessary for the sponsor to assess the degree to which the overall program fulfills its CME mission. It will also guide the planning of future activities and permit rational decisions about improving the educational program.

Guidelines

This Essential requires that the sponsor periodically review the extent to which the sponsor's educational goals for the overall program of CME, as contained in the mission statement, are being achieved. The sponsor should do this annually. In order to evaluate the effectiveness of the overall CME program, the sponsor must evaluate individual CME activities which have been planned and conducted. These evaluations must assess the extent to which the educational objectives have been met, the quality of the educational process, and the participants' perceptions of enhanced professional effectiveness.

Evaluation methods must be appropriate and consistent in scope with the educational activity. A well-constructed evaluation form completed by participants at the conclusion of the educational activity provides useful data. Often the evaluation form also provides an opportunity for participant suggestions for future educational activities. Immediate in-depth evaluation by selected participants, as well as follow-up surveys, may be very helpful.

If the educational objective concerns the learning of a skill, direct observation of the participant's ability to perform that skill is an excellent method of evaluation.

Tests may be used when appropriate. It is difficult, however, to construct a valid and reliable test, and as a result, data from tests are often questionable. The sensitivity of participants should be considered. Care should be taken that testing does not adversely affect the physician's desire to continue learning.

Although the ultimate purpose of continuing medical education is to improve medical care, measurements of physician performance, the quality of medical care and patient outcomes should not be the only criteria used in assessing the quality of the educational activity and of the degree of learning by participants. While keeping in mind that many factors beyond the control of CME planners influence medical care, sponsors are encouraged to attempt to assess the effect of their CME activities on medical care when this is feasible.

There are other evaluation techniques that are not based on educational objectives, but may be useful to the sponsor. Participant attention and enthusiasm, active involvement in discussion, the kinds of questions asked and comments made for instance, may be observed and recorded. The number of physicians who voluntarily return to a sponsor's CME activity may be another indication of quality.

The Essentials require that the sponsor demonstrate that evaluation data are used in planning future CME activities. Evaluation data collected but not used in future planning are worthless.

ESSENTIAL #6

THE SPONSOR SHALL PROVIDE EVIDENCE THAT MANAGEMENT PROCEDURES AND OTHER NECESSARY RESOURCES ARE AVAILABLE AND EFFECTIVELY USED TO FULFILL ITS CONTINUING MEDICAL EDUCATION MISSION. THE SPONSOR SHALL:

1. *Document an organizational structure for CME and its administration, designating an entity responsible for CME and delineating its authority.*
2. *Identify responsible individuals who will maintain continuity of administration.*
3. *Describe an internal review and control procedure, including budgetary practices, to ensure effective utilization of resources in fulfilling the CME mission.*
4. *Provide a budget for the overall CME program and its major components.*
5. *Utilize competent faculty.*
6. *Provide appropriate facilities for CME programs.*
7. *Have mechanisms to record and, when authorized by the participating physician, to verify participation.*

Explanation and Rationale

Whether sponsors of CME are large or small, adequate management and control are necessary to assure quality educational activities. In addition, adequate resources must be available in order for CME activities to be relevant, effective, and efficient for physicians.

Guidelines

ADMINISTRATION—The sponsor must document an organizational structure for CME and its administration, designating an entity responsible for CME and delineating its authority. This entity may be an individual or a committee. If an individual is designated, there should be an advisory committee, with a majority of physicians, which takes an active role in planning. Minutes of committee meetings should be kept. CME committees should have representation of departments and/or services when appropriate and feasible.

The organizational structure must clearly indicate the authority of the entity responsible for CME, and should show how this entity relates to the governing body of the organization and effectively supervises CME planning of other units of the organization. CME policies and procedures should be documented.

There should not be undue dependence on one individual so that in the event of absence or illness, the CME program flounders. The sponsor must identify responsible individuals who will maintain continuity of administration. Members of committees should be appointed so their terms expire on varying dates. Administrative staff support should be sufficient to fulfill the CME mission. The terms of office of the persons responsible for CME should be of sufficient duration to assure continuity of administration.

UTILIZATION OF RESOURCES—To ensure effective utilization of resources in fulfilling the CME mission the sponsor must have an internal review and control procedure. This procedure need not be elaborate. The procedure should permit the entity responsible for the overall program of CME to effectively monitor and supervise the planning and implementation of individual CME activities.

Included in the internal control procedure is preparation of a budget and the use of sound fiscal practices in administering the overall CME program. The budget should be adequate to meet the objectives of the mission statement. The sponsor is encouraged to have a separate CME budget, but should be able to, at least, clearly identify the CME budget when not separate from other items. Individual departments or services of an organization may have their own CME budgets, but the entity responsible for the overall CME program should have some responsibility for the allocation and utilization of resources.

COMPETENT FACULTY—The sponsor must utilize competent faculty. Faculty for a CME activity should be selected not only for their knowledge of the subject matter, but for their ability to communicate and to facilitate learning. The faculty's attitudes and manner of treating participants are also important considerations.

APPROPRIATE FACILITIES—Sponsors must provide appropriate facilities and materials for CME activities. Appropriate means conducive to learning. As an example, access to an adequate, up-to-date library and audiovisual facilities is important.

Facilities may be selected for a CME activity at a site which offers opportunities for recreation and relaxation. These opportunities should complement, rather than detract from, the CME activity itself. Publicity should present the CME activity as the major incentive to physicians who may choose to participate.

RECORDS OF ATTENDANCE—The sponsor must have a mechanism to record physician participation at CME activities. Records should be kept for at least six years. Sponsors must have a mechanism to verify physician attendance when authorized by the participating physicians.

ESSENTIAL #7

THE SPONSOR SHALL ACCEPT RESPONSIBILITY THAT THE ESSENTIALS ARE MET BY EDUCATIONAL ACTIVITIES WHICH IT JOINTLY SPONSORS WITH NON-ACCREDITED ENTITIES. THE SPONSOR SHALL:

1. *Provide evidence that it participates integrally in the planning and implementation of each jointly sponsored CME activity.*
2. *Conduct an evaluation of each jointly sponsored CME activity.*

Explanation and Rationale

An accredited sponsor may be asked by organizations which are not accredited to jointly sponsor CME activities, so they may have accredited sponsorship. When an accredited sponsor agrees to joint sponsorship it must provide assurance that the ESSENTIALS are met.

Guidelines

The Essentials require that a sponsor accept responsibility that accreditation standards are met by CME activities it jointly sponsors with non-accredited institutions and organizations. An accredited institution or organization has the same responsibility for an activity it jointly sponsors as for an activity it sponsors. The sponsor should provide information on these jointly sponsored activities when resurveyed for accreditation and must demonstrate that it has participated integrally in the planning and implementation of these activities.

Jointly sponsored activities must be consistent with the sponsor's mission statement. The sponsor must conduct an evaluation of each jointly sponsored CME activity in the context of its mission statement.

The name of the accredited sponsor should appear on all promotional materials and on the printed program of the jointly sponsored activity. If more than one accredited sponsor jointly sponsors a CME activity, one should assume responsibility for the activity and this should be clearly indicated on the promotional materials and printed programs.

Some local chapters or affiliates of national organizations are neither independently accredited nor specifically included in the accreditation of the national organization. The accredited national organization should have care that it not be listed as the joint sponsor of CME activities of such local chapters or affiliates unless the requirements of this Essential are met.

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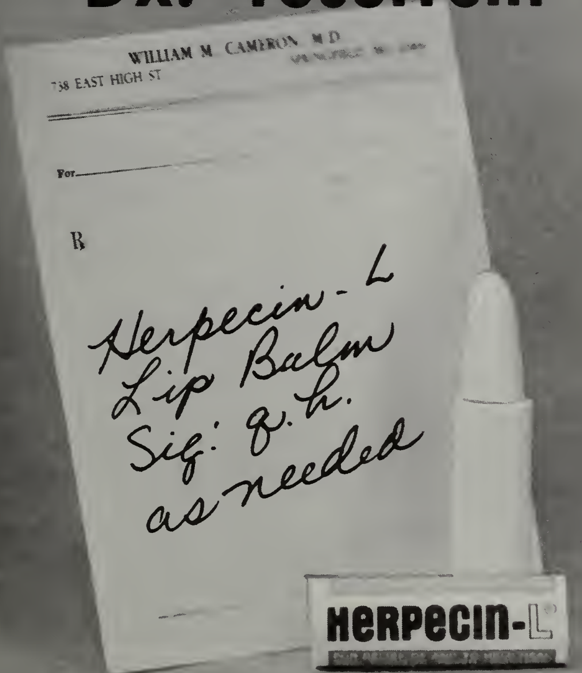

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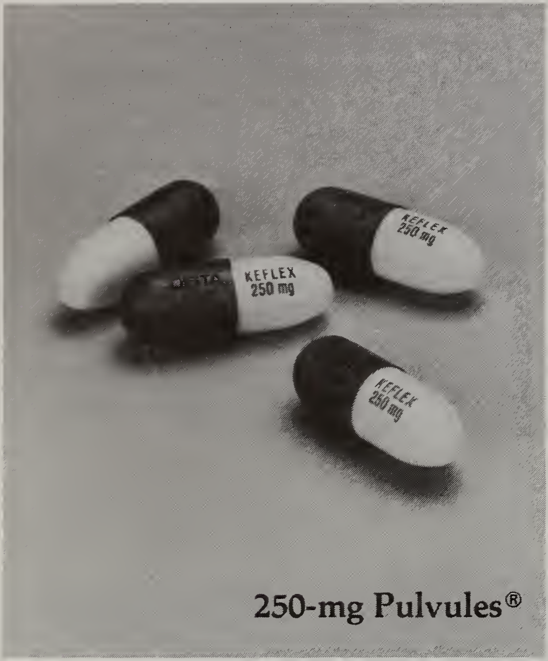

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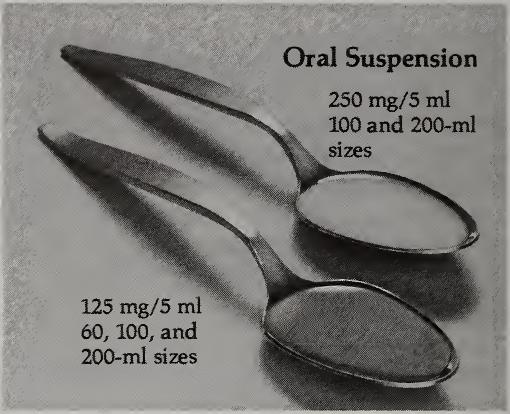

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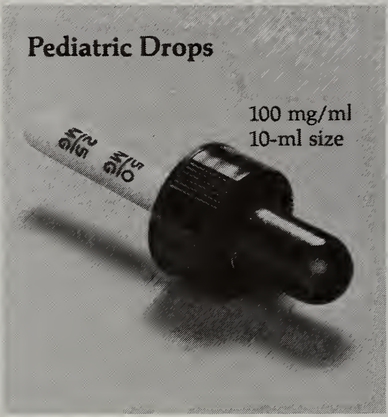

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Month in Washington

AMA Spearheads Freeze Opposition

Anticipating renewed attempts to freeze Medicare payments to physicians and require assignment of all Medicare claims, the AMA called on physicians to notify Congress of their opposition to such plans.

AMA thus resumed in January a campaign that was deferred when Congress adjourned in November without acting on several proposals.

Nearly certain to be resurrected early in Congress, the various proposals are driven by a projected $200 billion federal deficit and an impending financial disaster in Medicare. They are attached to three major vehicles: the President's fiscal 1985 budget proposal; efforts to reconcile projected 1984 spending with Congressional budget targets; and a budget deficit reduction plan being pursued in the Senate Finance Committee.

In fighting the proposed changes in Medicare treatment of fees, the AMA and other physician groups concentrated on the mandatory assignment provisions which they regarded as major philosophical and contractual changes in Medicare.

The January letter to AMA members credits assistance from individual physicians as key in successful efforts to stop the enactment of mandatory assignment provisions last year. It observed that such proposals "could reduce the number of physicians in the Medicare program, and urged physicians to write their Congressman of their opposition to proposals: "that would take away or limit your freedom to choose assignment on a case-by-case basis; that would unfairly reduce compensation for your services; and that would limit the freedom of choice of Medicare patients."

* * * * *

More Baby Doe

Federal regulations were issued in January, but the "Baby Doe" controversy shows no signs of quieting.

The new regulations offer changes of style, not substance. Although the new rule says that hospital review boards can act as mediators in disputes over care, it retains the government's right of final say. The Department of Health and Human Services is still free to override the opinions of parents, physicians, hospital administrators, and even the review board.

Posted notices, although smaller and more discreet in location, will still publicize the toll-free, 24-hour HHS phone number. However, cases of suspected neglect may be reported to the hospital review board or state child protection agency instead of Washington, D.C. If federal HHS offices decide that neglect did occur, the hospital stands to lose all federal funds, including Medicare and Medicaid.

The rule's start-up date, set for Feb. 11, should be deferred, say a coalition of medical groups. According to a letter sent to HHS Secretary Margaret Heckler by the American Medical Association, the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, and the Association of American Medical Colleges, a deferral will give the courts time to decide whether Section 504 of the Federal Rehabilitation Act applies, as HHS claims it does.

The extra time would also give local ethical review boards a chance to offer advice about these critical care decisions, according to the coalition. Many of these committees are just now being established and could operate more smoothly without HHS breathing down their necks, they say.

Furthermore, a deferral would not affect the claimed authority of the government in the "Baby Doe" arena, the medical groups told Heckler. It is unlikely that a deferral would interfere with any life-saving measures, they added.

* * * * *

Medicare Physicians Lists Out

Medicare officials have called for preparation of directories of physician Medicare assignment rates.

The directories, compiled by the insurance plans which contract to administer Medicare, are not likely to be entirely satisfactory to either beneficiaries or physicians. However, Health Care Financing Administration (HCFA) officials say they are to be updated after June 1 and they regard this effort as a trial run.

Under the present arrangement, Medicare contractors will distribute their own directories of physicians in their area to Social Security offices and to state and area Agencies on Aging. Groups representing the elderly and state medical societies and health organizations can obtain a copy of the directory from the carrier, and individuals may examine the directories at the Social Security or AOA offices. HCFA also plans to make lists

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Prepared by the Washington, D.C.
Office of the American Medical Association

available for purchase, probably through the Medicare contractors.

HCFA provided only general instructions to the contractors, directing that the guides be understandable to the elderly and that they identify the percentage of assigned claims in increments of 10; i.e., from 0-10% to 90-100%. Data is provided on medical suppliers and other health care providers as well as physicians. Providers submitting less than 100 claims to Medicare in the previous year are not included.

In organizing the directories, some Medicare contractors provided extensive explanations of the types of data included and provided phone numbers for questions; others included only sketchy explanations. Some listed all physicians in the contractor area alphabetically; others broke the listing down into small geographic areas or organized according to specialty or percentage of claims accepted on assignment. Some did not even list the specialty.

* * * * *

Healthier America, but There's a Cost

Americans are healthier than ever, according to the annual report, "Health United States," released by the Department of Health and Human Services in January.

But the price tag for health care services also continues to climb, outstripping inflation, the report shows.

Health Status:

- After a temporary decline after the 1980 flu epidemic, American life expectancy has resumed its upward trend. Women born in 1982 can expect to live to age 78.2 years, up from 77.9 years in 1981. Men will live an average of 70.8 years, up from 70.3 in 1981.
- Infant mortality continues to decline, reaching 11.2 deaths per 1,000 live births, down from 11.7 deaths in 1981. But the mortality rate for black infants remains almost twice as high as for whites.
- Fertility climbed in the late 1970s, reversing the plummet of birth rates seen in the early part of the decade. Yet, it is far from the proportions of the "baby boom" of the 1950s. There were 15.9 births per 1000 population in 1980, compared to 25.0 births per 1000 population in 1955. The average number of births expected by women 18-34 years of age has decreased during the past decade from 2.6 in 1971 to 2.2 in 1980.
- Cardiovascular disease and cerebrovascular disease claimed fewer lives in 1982 than in 1981, from 196 to 190 deaths per 100,000 population and 38 to 36 deaths per 100,000 population, respectively. Malignant neoplasms have increased, however, from 131 to 133 deaths per 100,000 population between 1981 and 1982.

Health Care Expenditures:

- In 1982, health care expenditures in the United States totalled $322.4 billion, an average of $1,365 per person, and comprised 10.5% of the gross national product. By comparison, 1981 health care expenditures totalled $286.6 billion, an average of $1,225 per person, and comprised 9.8% of the gross national product.
- Medical care prices continued to increase above and beyond the inflation rate, the report said. Between 1981 and 1982, medical care prices grew 11.6%, compared to a 6.1% increase in the Consumer Price Index. In the prior year, medical care prices grew 10.8%, compared to a 10% increase in the overall index.
- Hospital care expenditures continue to claim the largest share of the health care dollar; 42% of all expenditures in 1982. Physician services, dentist services and nursing home care accounted for 19%, 6% and 9%, respectively.

Utilization of Health Care Resources:

- Cardiac catheterization among middle-aged and elderly men continues to increase rapidly. Between 1979 and 1981, cardiac catheterization increased 97% for men over age 65 and 34% for men aged 45-64. Coronary bypass surgery increased 27% for younger men and 89% for men over age 65.
- CAT scans among hospitalized persons doubled between 1979 and 1981, from 0.8 to 1.8 per 1000 persons in all age and sex groups.
- Diagnostic ultrasound among hospitalized women increased 91% between 1979 and 1981. The increase was particularly dramatic—126%—in women over age 65.
- Lens extraction among the elderly increased 30% between 1979 and 1981. Furthermore, 57% of these procedures were accompanied by the insertion of a prosthetic lens in 1981, compared with 36% in 1979.

Health Care Resources:

- The proportion of women among graduates of health professions' schools has increased steadily since the 1960s. The proportion of female medical school graduates jumped from 5% in 1955 to 23% in 1980.
- Compared to voluntary hospitals, both urban and rural public hospitals had higher newborn death rates and a greater incidence of low-birth-weight infants.
- In metropolitan areas, public hospitals treated more minority patients than voluntary hospitals (20% vs. 11%), more Medicaid patients (15% vs. 8%), and more uninsured patients (12% vs. 6%).

* * * * *

White House Accepts 'Inefficiency' Report

A White House review team says it has agreed at least in part to about 95% of the recommendations of a Presidential Task Force charged with "rooting out inefficiency in government." The White House has not yet reviewed a special report that strongly criticizes the new Medicare diagnosis related groups (DRGs) payment plan, however.

Furthermore, although both the President and his staff are publicly praising the President's Private Sector Survey on Cost Control, their support contains some carefully-worded caveats, and privately many Administration officials are questioning the group's recommendations.

A group of business executives headed by Peter J. Grace of the W.R. Grace Company, the Private Sector Survey produced 47 volumes and 2,500 recommendations they said could save the government $400 billion over three years. About $45 billion of the savings would come from health programs.

Critics have charged that the recommendations simply rehash suggestions that have been floating around Washington for years, that the savings are overstated, and that many of the proposals are politically impossible. Much of the savings would not accrue until well into the next century.

Much of the Commission's work was completed last summer and a team of White House and Office of Management and Budget staff have been reviewing the proposals made at that time. A White House spokesman said the review teams agreed in part with 95% of the recommendations for HCFA and PHS and 75% of those for the management of the Department of Health and Human Services.

Most of the recommendations contained many subproposals, however, and members of the review team hedge their estimates of approval rates for the Commission's proposals by noting that the reviewers agreed to "implement at some level" the overall recommendations. No specifics are available. The White House has not yet seen a just completed special report that strongly criticizes Medicare's diagnosis related groups payment scheme before concluding that its use is justified for "short-term crisis management."

For HHS as a whole, the Grace Commission called for a 20% reduction (1500 positions) in management staff, including the elimination of the Office of Assistant Secretary for Health. HHS Secretary Margaret Heckler announced earlier this year that in line with the Commission proposals, she is freezing hiring in her office.

For HCFA, major Commission recommendations included: moving away from fee for service reimbursement to physicians; reducing excess hospital capacity; reducing and consolidating HCFA staff; expanding the use of competitive bidding for contracts to administer Medicare; and expanding DRGs to cover all payers. The report called for experiments with physician reimbursement based on fee schedules and on preferred provider organizations.

The Reagan Administration has opposed expanding DRGs to all payers and in its final report, the Commission, without overtly withdrawing its earlier recommendation to expand the system, labeled this a "short term response" which in the long term should be replaced.

For the PHS, the task force recommended: limiting the administrative costs for National Institutes of Health research grants; revising payment procedures for contracted care under the Indian Health Service; reducing eligibility for Indian Health Service benefits; consolidating federal toxicology testing; eliminating staff; increasing funds collected from National Health Service Corps sites; and improving collection of student loans.

In other health-related recommendations, the commission suggested that the cost of federal employes' health benefits be constrained by permitting employes to change plans only once every two years and that a "health agency" be created within the Department of Defense. The new agency would manage what now amounts to four independent health systems within DOD.

The commission was particularly critical of the Veterans Administration Hospitals system, concluding that their average length of stay is probably too long and that VA hospitals are under utilized. It recommends converting VA hospital beds to long term care beds and said VA health facilities should be shared by active military personnel and dependents.

* * * * *

HHS Backs Away from Loan Suspensions

The Department of Health and Human Services, concerned over potential political ramifications, has backed down on its plan to suspend 37 medical schools from the $246 million federal student loan program.

HHS had said that it would penalize the medical and other health professions schools if they could not lower loan delinquency rates to 5% of money owed by January 1, 1984. Some 123 schools were informed in November that they had not met the standard and would be suspended if they could not meet the target or cut delinquency rates in half by December 31.

A flurry of meetings between the White House, its Office of Management and Budget and HHS has now brought another postponement of the deadline—to December, 31, 1984.

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Hospitals Win/Lose Under Final DRGs

Hospitals got several things they asked for in the final regulations for medicare's new fixed-price payment system, but they'll have to live with a $24 million reduction in reimbursement next year.

The final regulations for the Diagnosis Related Groups (DRGs) published in the Federal Register January 3 offer several important changes in the regulations in effect since October 1. The new rules are expected to cut Medicare payments to hospitals by more than $100 million a year after 1986.

Hospitals generally were pleased with changes that loosen the criteria for exemptions for DRGs for certain types of hospitals, that permit hospitals to charge Medicare patients for requested services the hospital and physician have found unnecessary, and modify the calculation of payments for unusually lengthy or costly cases. Some physician groups, including the AMA, commended HCFA for modifications relating to indirect medical education costs, but they reiterated their opposition to the "radical restructuring" of the health care system under DRGs.

Both hospitals and physician groups are unhappy about an OMB-instigated modification that hospital experts predict will reduce the payment per Medicare case by $9 to $13 and decrease total Medicare payments to hospitals by $24 million next year. The diminished payments result from a decrease in the inflation update for DRG rates from the 11.7% published in the interim regulations to 10.9% in the final regulations.

Though critical of the precedent set by the reduction in the inflation factor, hospital officials say its initial impact is outweighed by their success in renegotiating the way DRG payments are calculated for outlier cases that exceed normal lengths of stay or are unusually costly. In effect, the change means that during the transition to a totally national DRG rate, hospitals will be paid somewhat more for the bulk of their cases but will receive less for outlier cases than under the interim regulations.

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Abortion Foes Rally Again

With the presidential elections quickly approaching, the issue of abortion once again has become a rallying point for special interest groups.

Abortion opponents plan to support President Reagan for a second term. Recently about 30 members of the March for Life, Inc., met with Reagan, asking him to stop all funding for abortion and support a "human life amendment." In his State of Union address, Reagan said he had "joined bipartisan efforts to restore protection of the law to unborn children."

Additionally, the nation's largest anti-abortion political action committee recently sent black wreaths to Congressional offices, along with a note advising them that their voting records have "contributed to the slaughter of 15 million tiny Americans." This PAC, which ranks second in nationwide independent PAC expenditures, will target for defeat 12 still-unnamed members of Congress.

Abortion supporters such as the National Abortion Rights Action League (NARAL) say they will support almost any Democratic candidate opposing Reagan. All Democratic candidates except former Florida governor Rubin Askew defend abortion rights. NARAL is concerned that Reagan will have the opportunity to appoint two to four new Supreme Court justices in the next term, which could shift the court majority from a pro-abortion to anti-abortion stance.

The group plans to spend $400,000 this year to defeat Sen. Jesse Helms (R-NC), Sen. Roger Jepsen (R-Iowa), and Rep. James Oberstar (D-Minn) and support Sen. Charles Percy (R-Ill) and Rep. Paul Simon (D-Ill), among others.

* * * * *

Diet/Drug Studies Reduce Heart Attack Risk

Corornary heart disease can be prevented in men at high risk by lowering blood cholestrol levels through diet and drugs, according to a government study released in January in the pages of the Journal of the American Medical Association.

Men receiving the anti-cholesterol drug cholestyramine experienced a total of 155 fatal and non-fatal heart attacks compared to 187 attacks experienced by men receiving a placebo, an NIH study found.

Investigators calculated that the drug produced a 24% reduction in fatal heart attacks and a 19% reduction in non-fatal heart attacks.

There were other indicators of reduced risk: persons receiving the drug experienced a 24% reduction in positive ECG, a 20% reduction in angina, and a 21% reduction in coronary bypass surgery, compared to persons receiving a placebo.

"These results have the potential to markedly reduce the large number of heart attack deaths presently experienced in this country," said C. Edward Davis, Ph.D., deputy director of the Lipid Research Clinic Program at the University of North Carolina in Chapel Hill. Coronary heart disease is responsible for more deaths in the U.S. than any other disease: one per minute, or more than half a million each year.

Of the 560,000 persons who die in the U.S. each year from heart attacks caused by atherosclerosis, an estimated 100,000 could be saved by the study's anti-cholesterol regimen, said Basil Rifkind, M.D., of the National Heart, Lung and Blood Institute in Washington, D.C.

The study was large and complex: 3,806 participants visited 13 medical centers across the U.S., collectively making 193,000 clinic visits, generating over 1 million data forms, giving 341,000 blood samples, and undergoing 72,000 electrocardiograms.

Participants were men aged 35 to 59 who had blood cholesterol levels of at least 265 mg/dl, but no clinical evidence of disease. The group was divided evenly into two identical subsets: half received diet instructions (restricted to 400 mg of cholesterol per day) and a placebo while the other half received identical diet instructions and the drug cholestyramine. The study was double-blind. Each patient was followed at least seven years; a few were followed 10 years.

When both treatment groups were on diet only, there was an average 3.5% fall in total cholesterol and a 4.0% fall in LDL cholesterol for all persons. With initiation of drug therapy, differences in cholesterol levels between the two treatment groups became apparent during the first year and maintained that gap throughout the study. Differences in disease rates between the two groups became apparent by the third year and widened for the duration of the study.

It has long been accepted that high cholesterol levels are linked to elevated incidence of heart disease. However, it had never actually, been proven that cholesterol reduction causes a parallel reduction of disease. This study shows that, as a rough rule of thumb, each 1% fall in cholesterol level is associated with a 2% reduction in the rate of heart attack.

The study's findings should be extended to women and younger men with high blood cholesterol levels, the researchers said. People with more modest cholesterol elevation could also benefit by cholesterol reduction, they say.

* * * * *

New Anti-Smoking Gum

The Food and Drug Administration has approved a chewing gum containing nicotine to help physically dependent cigarette smokers.

Available only by prescription, the gum Nicorette does not eliminate the desire for a cigarette but can provide a short-term alternative source of nicotine. FDA officials say Nicorette is not addictive, however.

According to FDA, smokers who have a high physical dependence on nicotine are the most likely to benefit from use of the gum. Such persons typically smoke more than 15 cigarettes a day, prefer brands of cigarettes with amounts of nicotine greater than 0.9 milligrams each, and find the first cigarette in the morning the hardest to give up.

The gum should not be used by pregnant or nursing mothers, persons with certain heart conditions, persons with a disease that makes chewing difficult, and nonsmokers, according to FDA.

* * * * *

Hospital Mergers Increase Costs

Hospital mergers substantially increase Medicare and Medicaid costs, and federal rules governing accounting practices employed in such transactions should be tightened, according to Congress' General Accounting Office.

Anticipated for several months, the GAO findings focus on the Hospital Corporation of America's (HCA) acquisition of 54 hospitals from INA Corp. Earlier rumors about the upcoming report had led to a decline in HCA stock, but the new report has been revised. While it does estimate that the acquisition increased overall capital costs of the hospitals by about $55 million and questions some HCA accounting techniques, it stops short of alleging the practicies were illegal.

The report was requested by Rep. Willis Gradison (R-OH) of the House Ways and Means Committee, who said the present Medicare policy rewards "those who traffic in hospitals."

Although Medicare's new diagnosis related groups reimbursement will move hospitals away from cost-based reimbursement and pay a fixed price per case, the GAO findings are still relevant since capital costs will continue to be paid on a cost basis until 1986. Gradison said he will seek hearings in the Ways and Means Health Subcommittee and may introduce "remedial" legislation.

HCA officials responded they welcomed the hearings, had done nothing improper and don't expect any deterioration in HCA's "financial position."

* * * * *

FTC Study Hits Ophthalmologists

Opticians can fit contact lenses as well as ophthalmologists, at a lower cost to the consumer, according to a new Federal Trade Commission report. But the report has come under fire by ophthalomologists, who fear that its widespread acceptance could harm patients who need the medical supervision of a physician.

This finding, if accepted by FTC commissioners, could result in a loosening of restrictions on the business practices of opticians. An earlier but similar FTC report on eye glasses and eye examinations has become the basis for a new FTC rulemaking.

The FTC study said there is little difference in the quality of contact lens fitting performed by opticians, optometrists, and ophthalmologists. The majority of 500 contact lens wearers from 18 cities, when interviewed and examined, were found to have healthy eyes and well-fitting contacts. Only a handful of patients had serious ocular abnormalities; of these, most did not relate to contact lens wear.

There was a wide range in costs, however. The average price for lenses, including examination, ranged from $119 to $183 for hard lenses and from $150 to $234 for soft lenses. The FTC said that ophthalmologists were the most expensive, commercial optometrists were the least expensive, and opticians and non-commercial optometrists charged prices somewhere in between.

"The findings call into question claims that restrictions on contact lens fitting by non-physicians are necessary to protect the public," according to the report. Such restrictions may increase costs to consumers by limiting the choices available to them and reducing competition in the marketplace, the report adds.

Some states forbid opticians to fit lenses, while others permit opticians to fit lenses only under the supervision of an ophthalmologist or optometrist. In the remaining states, the restrictions are fuzzy; state courts have reached differing opinions.

Physicians dispute both the methodology and the conclusions of the study. Only an ophthalmologist has the medical training to handle complications or hard-to-fit patients, says the American Academy of Ophthalmology. Since the FTC questioned only persons who were wearing contacts at the time, it may have overlooked difficult cases, such as persons with unusual eye structure or pathology. An eyeglass wearer reading the report has no way of knowing if he is a problem-free lens wearer or if he may encounter difficulties, says the physicians group.

* * * * *

Pacemaker Abuses Hotline

The Health Care Financing Administration, which has been accused by some Congressional committees of inadequately policing rebates and other abuses in the cardiac pacemaker industry, has notified its Medicare contractors that rebates, kickbacks and other such industry practices may be subject to fines of $25,000 or five year prison terms.

A form letter to be sent to all the pacemaker suppliers covered by the contractor was included with the instructions. It suggests that these and other abuses can be reported on a fraud hotline maintained by the Health and Human Services Department's Office of Inspector General.

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The President's Page

Prospective Payment—Part III

The Hall of the House at the State Capitol on Wednesday, January 25, 1984 was the grandiose setting for the first act of the debate on the proposed "All Payor Prospective Payment System for Hospitals." Extensive media coverage that day noted that 400 or more interested parties jammed the public hearing site to present their positions before the Legislature's Public Health Committee.

The proponents included the Commission on Hospitals and Health Care, the Connecticut Business and Industry Association, the Insurance Association of Connecticut, the Connecticut Conference of Municipalities, and the Connecticut Coalition on Aging. Representing the opposition were the Connecticut Hospital Association, Blue Cross Blue Shield of Connecticut, Inc., the Connecticut State Medical Society, the Connecticut Nurses' Association, the Connecticut Small Business Association, and the Hartford County Medical Association.

The bill, LCO-212—An Act Establishing A Prospective Payment System For Hospitals, was held under wraps by the Commission on Hospitals and Health Care until less than a week before the public hearing. It contains provocative regulatory provisions that we should all note. Sec. 2(a) The Commission on Hospitals and Health Care shall require hospitals to submit medical record abstract and billing data and such other data it deems necessary for the development and implementation of the prospective payment system described in this act. (b) While individual patient data shall be kept confidential publicly available aggregate reports may include reports which identify hospitals and physicians. Sec. 3(b) In the event the Commission is unable to perform the computations in time to establish service revenues for the hospital fiscal year commencing October 1, 1985, it shall use the weights developed by a state to be determined by the Commission in place of the weights that would have been computed. Sec. 13. The Commission on Hospitals and Health Care shall contract with an organization to review hospital admissions and to determine the appropriateness of the admission. Sec. 18. Hospitals shall not have the right to appeal the diagnostic grouping system chosen by the Commission on Hospitals and Health Care, the weights assigned to diagnostic groups, or the proportion of peer group standard in the hospital's rate. Sec. 22. The sum of ________ dollars is appropriated to the Commission on Hospitals and Health Care for the purposes of this act.

In summary, these provisions will not provide complete confidentiality; may use data from a distant state that might not at all be appropriate to Connecticut; may permit the Commission to create its own peer review organization other than the Connecticut Peer Review Organization (CPRO); will even prohibit hospitals from appealing the Commission's decisions on the DRG groupings, and weight assigned to each group for reimbursement purposes. Proponents of this measure theorize that they will be able to establish prospective payment rates that will be cost-effective; however no solid statistical evidence supports this claim nor are they able to determine how much it will cost the taxpayer to implement the plan. The proposal would permit the transformation of the Commission from a regulatory body that reviews hospital budgets to a rationing board that writes its own rules to implement a new unproven rate-setting methodology, thus further extending its bureaucratic horizon and at a still unknown cost to patients and taxpayers that could well exceed any anticipated "savings."

The Society remains committed to the concept that appropriate quality hospital care should be provided to all who need it in a cost-effective manner. Our citizens are not demanding less hospital care, or lower quality care. On the contrary, when they or their loved ones are hospital patients, they rightfully expect all the appropriate high quality, state-of-the-art care available. This bill is in my opinion, the most important health care issue that Connecticut has to face, and I believe it is the responsibility of all our physicians, to present this bill before their legislators and their patients in its true and proper perspective, in order to ensure its sound defeat.

Daniel W. Doctor, M.D.
President

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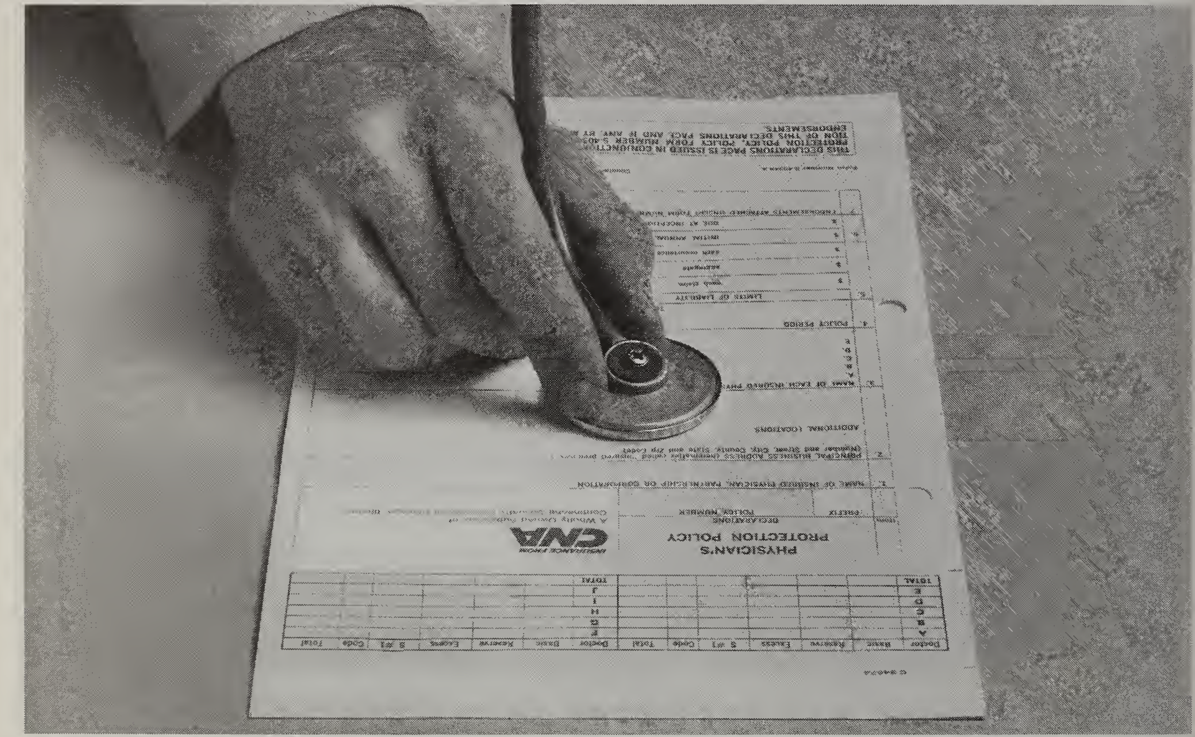

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Reflections from the Dean's Office

The Solution Problem

ROBERT U. MASSEY, M.D.

Like many other physicians, I acquired early in my professional life the habit of reading the obituary page of the morning paper. So it was that last month I noted the death at 78 of the Austrian-born writer and philosopher Manes Sperber in Paris. He had called himself an old revolutionary, but confessed that he had given up the idea of redemption through revolution. "I think that we are on this earth to seek," he said, "not necessarily to find."

It is not that the answers are always so hard to find; revolutions are founded upon simple answers; it is that they are usually so hard to pull off. The planners talk of implementation but rarely can figure out how to make things work; they start all over again redefining the problem to make it fit some remarkable solution that would implement itself.

We have had the problems of how to organize and how to pay for medical care for a long time; most of the solutions have been around for a long time too, but something keeps getting in the way of their being implemented, especially in accordance with the formulae of the true believers.

In 1927 a Committee on the Costs of Medical Care was formed with the support of several foundations and the United States Public Health Service; it included 48 members representing public and professional interests. One of its members, Lewellys F. Barker, a Professor Emeritus of Medicine at Johns Hopkins, wrote a book around this time, *The Young Man and Medicine,* which my father had given me to stimulate my already strong inclination toward medicine. Dr. Barker was evidently preoccupied with the Committee when he wrote:

> "The political problems that confront us are infinitely complex. They cannot be solved by sweeping formulae or fluent phrases. They demand for their solution the application of the method of science– definition of difficulties, accumulation of facts, and brooding over the facts to find the best method of procedure."[1]

The Committee on the Costs of Medical Care did not complete its reports until 1932. The recommendations in the Majority Report sound remarkably familiar: medical services "both preventive and therapeutic should be furnished largely by organized groups of physicians, dentists, nurses, pharmacists," with such groups organized "around a hospital, for rendering complete home and office care;" "all basic public health services–will be available to the entire population according to its needs." The Committee's report considered the organization of medical services, financing, and planning as necessarily related: "The Committee recommends that the costs of medical care be placed on a group payment basis, through the use of insurance, through the use of taxation, or through the use of both these methods" and "that the study, evaluation and coordination of medical service be considered important functions for every state and local community, that agencies be formed to exercise these functions–."

They considered professional education and urged emphasis upon health and prevention, and that the "social aspects of medical practice be given greater attention." In the final chapter, the Majority Report noted that, among other things:

> "The control of undesirable commerical enterprises in this field will depend largely on the watchfulness of the professional bodies,–and on the development of sound and successfully operating non-commercial plans."

There was a Minority Report, which questioned whether organization alone could accomplish the aims of the report, and expressed concern that medical insurance would increase the cost of medical care: "–the number of persons sick and the number of days' sickness per capita always increase under any insurance system." The minority also opposed organized group practice in favor of the general practitioner, but did support non-profit medical society plans for medical care. A second minority report submitted by the dental members advocated "compulsory health insurance under professional control." A JAMA editorial urged its readers to support the first Minority Report.[2]

The temptation is to remark that nothing changes. For over 50 years the solutions have been nearly the same, or at least variations on the same themes. But clearly the problems have changed. Since 1932 the Nation's population has doubled, the number of physicians has tripled, the ratio between specialists and general practitioners has been reversed, health insurance, Medicare and Medicaid pay most of the bills, biology has been reduced to a hard science, medical technology is a growth industry, and life expectancy has been increased by 15 years. The course of history moves right on past the planners, who, as someone remarked, are often left behind to face resolutely the problems of the 'thirties.

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ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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Connecticut's Informed Consent Case III

JOSEPH M. HEALEY, J.D.

The recent Connecticut Supreme Court decision dealing with informed consent[1] represents a major advance in clarifying this highly controversial area of medical law. Though somewhat incomplete and understated, the Court's treatment of the doctor's duty to discuss treatment alternatives is an important first step toward the development of a coherent body of law dealing with consent. Few practitioners are neutral about the nature and significance of informed consent. For its proponents, informed consent represents an essential commitment to the patient's dignity, well-being and self-determination in a modern doctor-patient relationship untainted by benevolent paternalism. For its opponents, informed consent represents an unfortunate fantasy which is, at best, unattainable and, at worst, harmful and undesirable. For Connecticut physicians, dialogue between proposents and opponents will now occur in a more concrete context, since the major impact of the Court's decision has been the explicit acceptance by the Court of the recent trend in law toward the "patient-centered" concept of consent which has been evolving throughout the United States during the past twenty-five years.

The basic facts of the case have been described in my recent columns. The central issue presented to the Court was the nature and extent of a physician's duty to advise a patient of diagnostic and treatment alternatives. Specifically, the Court was asked to determine the extent of a doctor's duty to disclose alternatives considered to be more hazardous than those proposed. In its decision, the Court restated its approval of Cardozo's root premise in American jurisprudence—that adult persons of sound mind have a right to make decisions about their lives—and proceeded to discuss the nature of the disclosures necessary for such decisions to be made. The Court clearly chooses to abandon the traditional medical community standard and accepted in its place the modern lay standard of disclosure. This standard requires that the doctor provide the patient with that information which a reasonable patient would find material for making such a decision. Failure to satisfy this duty would represent a breach of duty for which a physician could be held liable in malpractice.

The Court's decision clarified what had been an ambiguous situation. Without explicit judicial, legislative or administrative agency action, it was not clear that Connecticut would follow the modern trend in informed consent. This decision resolved that ambiguity while leaving a great deal of room for further development. One disappointment for me was the failure of the Court to make any apparent use of the work of the President's Commission dealing with either the contemporary doctor-patient relationship or consent. A second disappointment was the ambiguity about the precise nature of the doctor's duty to disclose. In a critical section of the decision, the Court cited parallel segments of three leading informed consent cases from other jurisdictions leaving unclear which, if any, represented the most accurate formulation of Connecticut law. Some physicians have expressed their concern that doctors must disclose all information which might have some bearing, however remote, upon the patient's decision. However, the Court appears to favor a standard of "reasonableness" in disclosure but fails to provide clear guidelines on how to satisfy such a standard. There remains much work for future cases.

One important aspect of the decision has implications beyond the area of consent. The practice of limiting the applicable standard of conduct to the practice of doctors in the same specialties practicing in the state of Connecticut was challenged by the patient-plaintiff as being arbitrary. The Court agreed that the time had arrived to broaden the geographical limitation to include the entire nation. Connecticut physicians will now be held to a national standard rather than a Connecticut standard. The greatest impact of this aspect of the case will be broadening of the pool of available experts for testimony in malpractice cases to include physicians who possess knowledge of the broader standard.

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JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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The Resident's Page

Support Your Local Housestaff

After making it through the rigors of medical school, finding and keeping a residency in one's field of interest has been taken for granted up to now, but such may not be the case for long. For the past fifteen years, medical school enrollment has climbed steadily, to reach a peak in 1983, and is expected to be fairly steady for the next five years. On the contrary, residency programs around the country are shrinking, so the former excess of available first year positions is now much closer than ever to the number of applicants.

A number of trends will bring these numbers still closer. Hospitals and medical schools are entering a period of "fiscal restraint" and postgraduate medical education is a likely target for cost cutting. The federal government, too has signalled its intentions by stating that Medicare fees to hospitals will not include reimbursement for educational expenses, and has done away with the direct support that funded many family practice and primary care residencies. Closed panel health care organizations, (like HMO's) and for-profit hospitals are also taking a larger share of the hospital business, and often have no place for house staff.

Residency directors nationally are working to preserve and improve their programs despite adverse conditions. However, residents themselves will have to take responsibility for their own and their patients' interests. We are all going to be facing the prospect of fewer residents, longer hours, cutbacks in ancillary services, and fewer educational resources. This point is not in the far off future, it is right now: there are physicians working in "volunteer" programs for want of a residency slot, and almost every program can point to holes in its faculty, services or physical plant due to lack of funds.

The only way for residents to cope is by working together. As a small and transient group within the hospital, an individual resident has little voice, and can be easily out-waited. A strong local housestaff organization is an ongoing entity to permanently defend residents, their education and the care they render their patients.

I would urge you all to support your local housestaff organization, and encourage more participation by more housestaff at all levels of hospital policy. You will not get everything you want; no area of health care will be unaffected by budget cuts. Don't let your residency bear an undue share of those cuts for want of representation at the decision-making level.

Lee R. Morisy, M.D., *President*
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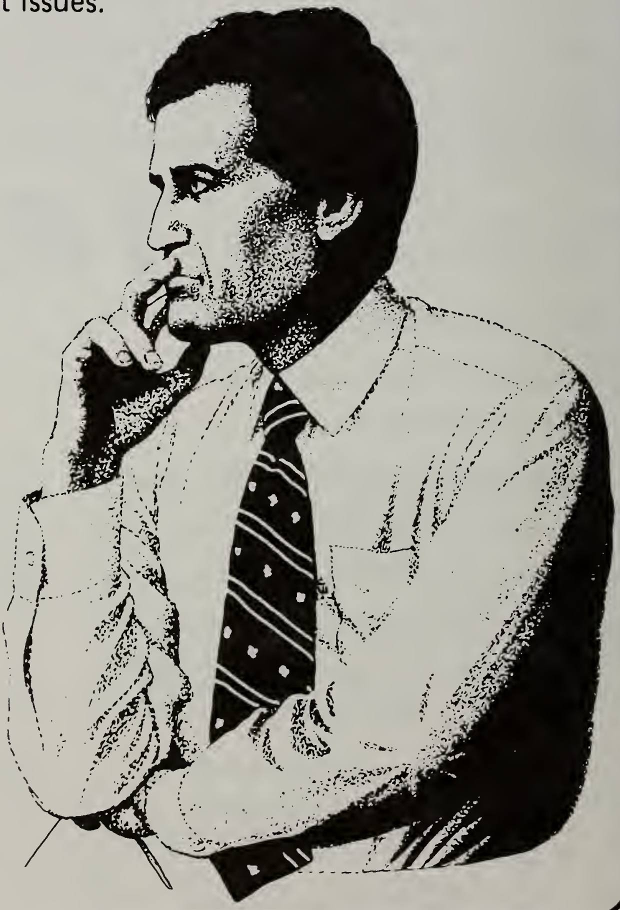

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Editorials

The Role of Mammographic Screening

While mammography was first performed on patients as early as 1930,[1] the modern era of breast imaging began with Egan's use of a high milliamperage, low-kilovoltage method of mammography.[2] Over the past two decades, the quality of mammographic imaging has markedly improved, making it a powerful diagnostic tool; and, when properly performed, radiation surface exposure has been reduced to less than 1 rad. Today, the value of mammographic examination in the detection of suspected breast cancer is well established. While the value of mammography as a diagnostic tool is universally accepted, controversy has, however, been generated over its potential use as a screening technique for detecting occult breast cancer in asymptomatic women. For example, guidelines from the American Cancer Society (ACS), the American College of Radiology (ACR), and the National Cancer Institute (NCI) vary on the issue of mammographic screening of younger (age 35-49) asymptomatic women.

All three agencies concur, however, on the use of mammography as a screening procedure in "high risk" categories. These are: (1) women aged 35 or more with a history of cancer of one breast, (2) women aged 40 or more with a family history of breast cancer, and (3) asymptomatic women aged 50 or more. Since advancing age is an important risk factor for breast cancer and the results of the Health Insurance Plan (HIP) randomized trial of New York[3] demonstrated that mortality from breast cancer could be reduced by 30% in women (over age 50) screened with physical examination and mammography, the practice of mammographic screening of asymptomatic women 50 years or older, therefore, is clearly justifiable. Earlier data analysis[3] of the HIP study failed to show any statistically significant benefit for women aged 40-49. A subsequent analysis of the HIP study, interestingly, indicated lower breast cancer mortality in the mammography group aged 40-49 as the duration of follow-up increased.[4] Reservations about this gain have been raised, however, based on the observation that the decrease in mortality in women aged 45-49 was concentrated among cases diagnosed after they reached 50 years of age. As a result of this reservation and since definitive results of other randomized studies on this subject are not yet available, recommendations on screening mammography of women in this age group have differed between the NCI on one side and the ACS and ACR on the other. The guidelines of the ACS[5] and the ACR[6] suggest a baseline mammogram for women aged 35-40 and periodic mammograms at one to two year intervals for women aged 40-49. This position has also been endorsed by the American Association of Family Practitioners. The NCI neither makes a recommendation on baseline mammography nor suggests periodic mammograms in all asymptomatic women aged 40-49.

We do not view these differing guidelines to represent a major dispute. Instead, we sense a cautious approach in the NCI guidelines. The apparent reluctance of the NCI to endorse the blanket use of baseline mammography or periodic mammography in women 35-49 is understandable since no data are currently available on the benefits of such screening in terms of definitive decrease in mortality. We note, on the other hand, an equal reluctance by the NCI to reject outright the use of screening mammography in younger women. Indeed, the Office of Cancer Communications in the NCI suggests " a physician may recommend routine examination with mammography for women not in the high risk groups because it is very effective in finding early breast cancer."[7] We wish to emphasize the effectiveness of modern mammography in finding early breast cancer, a point amply documented by the Breast Cancer Detection Demonstration Project (BCDDP).[8] Although not a controlled study, the BCDDP demonstrated that one third of the cancers detected were in women under 50 and a significant percentage of these were detected by mammography alone. A large number of those non-palpable lesions were minimal cancers (less than 1 cm) or in-situ cancer.

From a pragmatic viewpoint, the notion that breast cancer is "incurable" and, hence, its early detection offers no advantage, is unacceptable. Further, neither the risk of mammography, when properly performed, nor its cost in economic terms ($70-$225 per examination according to a 1982 survey of 14 geographic areas) appear to be prohibitive. It is, in fact, more likely that women would develop spontaneous breast cancer than cancers resulting from mammography. Considering the prevalence of breast cancer (one out of 11 women being at risk) and the potential benefit of reduced mortality from early detection, the risk benefit ratio, in our judgment, appears to favor mammographic screening.

Several randomized breast cancer screening projects are underway. While some of these trials demonstrate a significant increase in the detection of less advanced cancer in patients screened with mammography in contrast to the non-screened control groups, mortality rates will not be available for several years. In the interim, prudence would dictate that mammographic screening be performed on all asymptomatic women within the guidelines endorsed by the ACS and the ACR. Revision of these guidelines may be required in the future as warranted by results from the ongoing studies.

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Mammography Guidelines: 1983

Background Statement and Update of Cancer-Related Checkup Guidelines for Breast Cancer Detection in Asymptomatic Women ages 40-49.

The following statement was approved by the Board of Directors of the American Cancer Society on June 4th, 1983:

> Mammography has made significant contributions to the diagnosis of breast disease in *symptomatic* women and in the detection of breast cancer in asymptomatic women age 50 years or older. However, in younger asymptomatic women, the role of mammography is less clearly established by controlled randomized trials and the hypothetical projection of risk from radiation.
>
> However, recently reported results from the American Cancer Society-National Cancer Institute Breast Cancer Detection Demonstration Projects indicate that one third of the breast cancers occurred in women between the ages of 35 and 49 years, and most of these lesions were either in situ or did not involve the regional lymph nodes. Most of the cancers were detected by mammography, and a much higher percentage were detected by mammography alone than by physical examination alone.
>
> There has been remarkable improvement in the quality and diagnostic accuracy of mammography in recent years, concomitant with a marked reduction in the radiation dose – one rad or lower at the midbreast, using a two-view examination. Available information suggests that the risk of inducing breast cancer by the low doses now possible with modern mammography – if it exists at all – is minimal.
>
> Because of the detection of some palpable and small breast cancers and because of the reduced radiation exposures now possible with optimum mammographic technique and carefully monitored equipment, a favorable benefit/risk ratio can be expected in women beginning at age 40 and older.
>
> To provide guidance to physicians and women, the Society recommends a modification of its current guidelines for asymptomatic women ages 40 to 49. This guidance is based on careful examination of available data and may be modified when and if new information becomes available.
>
> The American Cancer Society is now recommending the following:
>
> *That the Cancer-Related Checkup Guidelines for breast cancer detection be modified for asymptomatic women ages 40 to 49 years. Women in this age group should have a physical examination of the breast annually, and mammography should be performed at intervals of one to two years.*

American Cancer Society

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

DRINKING AND/OR DRIVING

To the Editor: In September, 1983, The Medical Staff of the Danbury Hospital publicly stated that there was need for change in the statutes relating to driving while intoxicated. It was their recommendation that "conviction for driving while intoxicated should be accompanied by suspension of the license to drive until such time as the offender can offer proof of successful rehabilitation." It was also stated that "the medical profession views alcoholism as a disease. The profession abhors punishment in the sense that it is not a proper therapeutic mode." In carrying this concept further, I recently proposed to Governor O'Neill's office the following simple plan, bearing in mind that alcoholism is a treatable disease and that driving under the influence is one symptom of it.

If someone who is arrested for driving erratically has a blood, urine, or expired air-alcohol concentration over legal limits, the license to drive should be suspended immediately. The length of time of such suspension must be dependent on the impaired person's reaction to treatment of the underlying disease of alcoholism.

The function of the judiciary should be to establish the fact of driving while impaired, suspend the right to drive, and refer the individual for treatment. Today there are many resources available for outpatient as well as inpatient therapy of alcohol and drug-related disease.

The first offender's progress in treatment should be reassessed at the end of 90 days. If a professional counselor reports adequate positive response to treatment in a formal report to the Department of Motor Vehicles, the right to drive could be reinstituted at that time. Recidivism would result in suspension of the right to drive for a minimum of one year. Reinstitution of licensure would again be dependent upon a favorable response to treatment attested to by a professional counselor. Irrevocable suspension of licensure would follow a third incident. This approach affirms the disease concept of alcoholism, while protecting the public by removing the dangerous driver from the highways.

Rather than fine the offender, the funding for such mandatory treatment would be paid for by the impaired driver in whole or part. In those cases in which funds are unavailable, an increase in the tax on alcohol could provide a revolving loan fund. The monies used for treatment could be repaid with nominal interest following the return of the offender to productive employment.

Henry N. Blansfield, M.D.

Danbury, CT

SPECIAL NOTICE

Cardiovascular Symposium
May 2, 3, 1984

The 20th Annual Cardiovascular Symposium sponsored by the Section of Cardiology, Saint Francis Hospital and Medical Center, Hartford, CT. will be held at the Hunt Memorial, Hartford Medical Society, 230 Scarborough St., Hartford, CT on May 2 and 3, 1984.

The Fee is $60.00

Contact: Robert M. Jeresaty, M.D., Director, Section of Cardiology, Saint Francis Hospital and Medical Center, 114 Woodland St., Hartford, CT 06105.

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4/3-10/16	Emergency Medicine Board Review (Tuesdays, 4-7 P.M.)
4/26-4/28	Update in Dermatology
MAY	
5/3-5/5	The Medicolegal Autopsy
5/10-5/13	CT of the Spine (Grand Hyatt Hotel)
5/19-5/20	Review of Basic Sciences in Urology
5/19-5/20	Proficiency in Cytopathology
5/19-5/20	Practical Management of Gynecologic Endocrine Disorders and Infertility
JUNE	
6/4-6/6	Obstetrical Ultrasound
6/4	Interventional Radiology and Digital Imaging
6/5-6/9	Computed Tomography Head to Toe with MRI
6/11-6/15	Emergency Medicine
6/23 & 6/24	Chymopapain I & II (2 intensive 1 day sessions)
6/25-6/28	Pediatric and Adolescent Medicine
AUGUST	
8/27-8/31	Radiation Physics and Biology

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NOTICE TO CONTRIBUTORS

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult INFORMATION FOR AUTHORS. This material may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:
J. Alfred Fabro, M.D., Editor
Connecticut Medicine
160 St. Ronan Street
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192nd ANNUAL MEETING
OF THE
CONNECTICUT STATE MEDICAL SOCIETY
PARKVIEW HILTON HOTEL, HARTFORD
Thursday, May 10, 1984

GENERAL SCIENTIFIC PROGRAM

MORNING SESSION

8:15 REGISTRATION—Mezzanine

8:30-10:00 MEETINGS OF SECTIONS OF THE SOCIETY

10:00 INTERMISSION TO VISIT EXHIBITS

BALLROOM

10:20 CALL TO ORDER AND WELCOMING REMARKS
President,
Connecticut State Medical Society

Presiding: Norman J. Marieb, M.D.,
New Haven

SYMPOSIUM—THERAPY OF CORONARY ARTERY DISEASE

10:30 CALCIUM CHANNEL BLOCKERS
FRANCIS KLOCKE, M.D.,
Professor of Medicine and Physiology,
State University of New York

11:00 CORONARY ANGIOPLASTY
JOHN S. DOUGLAS, M.D.,
Assistant Professor of Medicine (Cardiology),
Emory University

11:30 BY-PASS SURGERY
FLOYD LOOP, M.D.,
Head of Department Thoracic &
Cardiovascular Surgery
Cleveland Clinic Hospital

12:00 PANEL DISCUSSION:
Francis Klocke, M.D., Buffalo, NY
John S. Douglas, M.D., Atlanta, GA
Floyd Loop, M.D., Cleveland, Ohio

12:30 INTERMISSION TO VISIT EXHIBITS

1:00 LUNCHEON

AFTERNOON SESSION

Presiding: Franklin Robinson, M.D., New Haven

SYMPOSIUM—CRITICAL ETHICAL DECISIONS AND CURRENT MEDICAL TREATMENT

2:00 JOSEPH M. HEALEY, JR., M.D.,
Associate Professor, Department of
Community Medicine and Health,
University of Connecticut
Health Center

2:30 ANGELA R. HOLDER, L.L.M.,
Counsel for Medical-Legal Affairs,
Professor of Pediatrics (Law),
Yale University School of Medicine

3:00 DOCTOR RICHARD NOLAN,
Professor of Philosophy and
Social Sciences
Mattatuck Community College

3:30 PANEL DISCUSSION:
Joseph M. Healey, Jr., M.D.,
Farmington, CT
Angela R. Holder, L.L.M., New Haven, CT
Doctor Richard Nolan, Bristol, CT
INTERMISSION TO VISIT EXHIBITS

4:00 MEETINGS OF SECTIONS OF THE SOCIETY

IN MEMORIAM

DAMIANI, RUDOLPH A., Tufts, 1933. Dr. Damiani was general practitioner in the New Haven area. He was a practicing physician on the staff at St. Mary's Hospital for 50 years. Dr. Damiani was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Died February 3, 1984 at the age of 75.

DUDAC, THOMAS, Georgetown, 1933. Dr. Dudac was a general practitioner in the Southington area since 1934. He was a member of the staff at Bradley Memorial Hospital, and was also a former president and secretary of the staff. Dr. Dudac was health officer of Southington from 1952 to 1955, and had worked in the development of the Salk Vaccine. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died December 22, 1983 at the age of 79.

HERMAN, MYER, Trinity College/University of Dublin, Ireland, 1939. Dr. Herman served as Bridgeport city health director since 1975. A native of England, he was decorated for distinguished service in World War II. Dr. Herman was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Died January 9, 1984 at the age of 69.

HIDEN, ROBERT B., University of Virginia, 1923. Dr. Hiden was on the Medical Staff of the Silver Hill Foundation in New Canaan for 24 years and prior to that, he had practiced internal medicine in Washington and from 1930 to 1943 practiced psychiatry in Massachusetts. He was a member of Phi Beta Kappa, Alpha Omega Alpha, the medical honor society, Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Died February 3, 1984 at the age of 86.

HURWITZ, GEORGE H., University of Maryland, 1933. Dr. Hurwitz was an allergist in the Hartford County area since 1936. He was a World War II veteran, serving in the Medical Corps. Dr. Hurwitz was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Died January 26, 1984 at the age of 75.

LEWICKI, EDWARD S., Georgetown, 1935. Dr. Lewicki was a general practitioner in the Waterbury area for 50 years. He was a state police surgeon. Dr. Lewicki was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Died February 6, 1984 at the age of 79.

NOLAN, JOHN O'LEARY, Tufts, 1940. Dr. Nolan was a general surgeon in the Hartford area. He was an attending surgeon at St. Francis Hospital. Dr. Nolan was a Major in the Medical Corps., U.S. Army Air Force from 1942 to 1946. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died December 31, 1983 at the age of 70.

RANGANATHAN, VASUDEVA, Madras Medical College, 1953. Dr. Ranganathan practiced emergency medicine and surgery in the Hartford area since 1972. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Died January 26, 1984 at the age of 60.

SHEA, VINCENT T., Tufts, 1931. Dr. Shea was a general surgeon in the Waterbury area since 1931. He was attending surgeon and at one time, chief of staff of St. Mary's Hospital. Dr. Shea was prominent in the March of Dimes campaign for more than 20 years and under his leadership Waterbury usually led the state in raising funds to fight polio. He was a Fellow of the American College of Surgeons, a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died December 13, 1983 at the age of 78.

SIMSES, JOHN P., Tufts, 1937. Dr. Simses was an ophthalmologist in the Fairfield area for 40 years. He was senior attending at Bridgeport hospital. Dr. Simses was a member of the American Academy of Ophthalmology. He served as chairman of the Connecticut State Medical Society's eye section and eye care committee. Dr. Simses was a veteran of World War II and had served as a captain in the medical corps. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died December 22, 1983 at the age of 70.

WRIGHT, RALPH C., College of Physicians and Surgeons, 1943. Dr. Wright was an obstetrician and gynecologist in the New Britain area since 1950. He spent two and a half years as a lieutenant in the U.S. Navy in World War II and served in the Pacific Theater. Dr. Wright was senior attending at New Britain General Hospital and served as chief of obstetrics and gynecology from 1963 to 1970 and as associate chief from 1970 to 1976. He was a major contributor to the design of the new labor delivery suite for the Lamaze method childbirth. Dr. Wright was appointed a clinical associate to the University of Connecticut Medical School in 1970-71 and an associate clinical professor in 1977. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died December 29, 1983 at the age of 66.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511 Telephone 865-0587

Timothy B. Norbeck, *Executive Director*
Josephine P. Lindquist, *Associate Executive Director*

Francis G. Sweeney
Assistant Executive Director
Public Affairs

Robert J. Brunell
Assistant Executive Director
Scientific Activities

Richard J. Fiorentino
Coordinator
Special Services

CALL

ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1984 Annual Meeting of the House of Delegates will be held at the Parkview Hilton Hotel, Hartford, commencing at 12:30 P.M. on Wednesday, May 9.

Daniel W. Doctor, M.D., President
Lawrence B. Ahrens, M.D., Speaker of the House
Norman A. Zlotsky, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides:

Resolutions may be introduced by any Active or Life Member or student members or postgraduate physician members of the Society, in compliance with the following provisions:

a. *All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*

b. *Component county associations or the student members of postgraduate physician members, whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.*

c. *Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.*

d. *Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

Council Meeting

Wednesday, February 1, 1984

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahrens, Alisberg, Beck, Bobruff, Canzonetti, Concannon, Dardick, Doctor, Freedman, Friedberg, James, Kamens, McDonnell, Mendillo, Orphanos, Parrella, Petrie, Ragusa, Sadowski, Sullivan, Jr., Sweet, Villa, Waldron, Whalen, Jr. and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Sweeney, Mr. Tomat (FCMA), Mrs. Harney (NHCMA), Mrs. Clark (HCMA) and Mrs. Sandler (President, Auxiliary).

Absent were: Drs. Ahamed, Czarsty, Fabro, Kaess, Keefe, Reyelt, Jr. and Sharon.

Reports from Physicians Serving on State and Federal Agencies

Dr. Eslami reported on the January meeting of the Statewide Health Coordinating Council (SHCC) drawing particular attention to two matters of interest: 1) Designations of Health Manpower Shortage Areas (HMSAs) in Connecticut; and 2) a SHCC meeting slated for Friday, February 17th, 2-5 P.M., Meriden Town Hall, at which the "ALL-PAYOR" Prospective Payment legislation will be discussed by CHHC, CBIA, IAC, BC/BS, CHA and CSMS representatives. He indicated that the meeting would be held only if it was an educational seminar and the CHA participated.

Mr. Fiorentino reviewed his staff report briefly and noted that the "Baby Doe" regulations had been passed but that the AMA remained opposed to them and expected a vote in the future and that the Society would be notifying its constituents when appropriate action should be taken.

Report of the President

CHA Meeting on 1/24/84: President Daniel W. Doctor, M.D., reported on a meeting for legislators sponsored by the Connecticut Hospital Association. The speakers, in addition to Dr. Doctor, were representatives of the CHA and Blue Cross/Blue Shield. All speakers addressed the "ALL-PAYORS" legislation being considered by the legislature.

Hearing of Public Health Committee in Hartford on 1/25/84: Dr. Doctor also discussed a hearing on the "All-Payors" legislation held by the Public Health Committee of the legislature. Other speakers included representatives of CHA, Blue Cross/Blue Shield, CBIA, Hartford County Medical Association, and Gardner Wright from the Commission on Hospitals and Health Care.

Hartford Retreat on 1/28/84: Dr. Doctor was unable to attend a meeting held by the Hartford County Medical Association with representatives from business and the insurance industry, but Tim Norbeck represented CSMS at the Saturday session. Drs. Norman Alisberg and Lawrence Ahrens discussed the meeting and mentioned that another get-together of that type may be planned for a later date.

Tenure of AMA Delegates

After discussion, it was VOTED to rescind the previous action (12/15/83) of the Council to limit the years of service in the CSMS AMA delegation to eight (8) years.

Report from Committee Legislation

Isadore H. Friedberg, M.D., Chairman of the CSMS Committee on Legislation, reported on the committee's recent activities. He mentioned a letter of resignation had been received from William Mac Shepard, a long time member of the committee. It was agreed that a letter over the President's signature should be sent to Dr. Shepard accepting his resignation with regret and expressing thanks for his years of service to the committee.

Dr. Friedberg apprised the Council that it was the desire of the Committee on Legislation to instruct the Society's legislative counsel to check into the feasibility of introducing tort reform legislation into this session of the Connecticut Legislature. Legislative Counsel reported that because of the technicalities of this years short session, it would not be possible to introduce such legislation. There may be a legislative study commission formed in the summer months to further discuss the subject.

Definition of Death legislation will be introduced by the CSMS, as it was during the 1983 legislative session. Living Will legislation will be introduced again by Senator Rogers which will be supported by CSMS. Parties to proposed impaired physician legislation are attempting to work out the confidentiality aspects.

After discussion of the proposed "All-Payor" legislation and tort reform, the following motions were adopted:

It was VOTED to request the Committee on Statewide Medical Planning to study the position on policies that CSMS should take in the future relative to health care costs and report back to the Council within ninety days with a progress report.

It was VOTED to send a legislative report RE tort reform to the Section on Orthopaedics and other interested sections inasmuch as the Society was advised by Legislative Counsel that it would not be possible to introduce tort reform during the current short legislative session.

It was VOTED that CSMS sponsor a legislative (informational) seminar for State legislators to be held by the end of February.

Detoxification Facilities for Drug Addicts

Jerome Bobruff, M.D., advised the Council that there was no detoxification facility for heroin addicts in all of Southeastern Connecticut but that plans were being discussed to establish one at Norwich State Hospital. It was VOTED to recommend a detoxification facility at Norwich State Hospital to serve Southeastern Connecticut and that the Commissioner of Health and Commissioner of Mental Health be so informed.

Group Term Life Insurance

After discussion and a comparison of premiums and related information, it was VOTED to endorse the Loyalty contract offered by the Ayr Agency for a life insurance program.

Rationing Hospital Care

It was VOTED that CSMS undertake a public member education effort to publicize information carried in the article from the January 5, 1984 issue of the *New England Journal of Medicine.*

Life Members

It was VOTED to receive for information the list of Life Members which is as follows:

Name	Town	Effective Date
Henry A. Adams	Cromwell	1/1/84
William T. Brown	Oxford	1/1/84
James C. Canniff	Torrington	1/1/84
Ruth T. Dwyer	Granby	1/1/84
W. Raymond James	Essex	1/1/84
Frederick C. Weber, Jr.	Greenwich	1/1/84
John H. Woodruff	Hartford	1/1/84
Daniel Young	N. Kingston	1/1/84

Miscellaneous

Mehdi Eslami, M.D., invited the Council members to the 200th anniversary celebration of the New Haven County Medical Association on March 22, 1984, at Sprague Hall at the Yale Commons. Mr. Norman Cousins will be the speaker at the black tie affair which will be followed by a dinner dance. Tickets are $35 per person and $70 per couple.

CSMS Section on Emergency Medicine

A letter was read from the secretary of the Section concerning the notice they received informing the group that this was the third year that they did not meet during the annual meeting of the CSMS which is usually cause to disband the section. Following review of the correspondence, it was VOTED to grant the Section one more year to comply with the CSMS bylaws.

Date of Next Council Meeting

The next Council meeting will be held on Thursday, March 15, 1984.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on February 1, 1984. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

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WANTED: Family Practice, General Practice or other physicians with broad based primary care experience, to work part or full time in an ambulatory care facility. Residents finishing in July '84 are also being sought to work in this excellent new facility in southern Connecticut. Please send copy of CT license and resume to: Marcus L. Schaefer, M.D., 56 MacArthur Road, Trumbull, CT 06611.

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Allergist, Dermatologist, Ob/Gyn, Internist needed as full-time staff members for growing centrally-located Connecticut HMO. Prestigious hospital affiliation. Excellent salary and benefits package. No fee. For more information contact Dr. Marci Goldstein, (212) 725-1000 collect.

Internist wanted as full-time Staff Physician for 500-bed multi-licensed, JCAH approved geriatric institution. Geriatric experience preferred. Will work standard workweek, rotation of evening and weekend call. Please send resume with salary requirement to: Director of Personnel, Masonic Home and Hospital, P.O. Box 70, Wallingford, CT 06492.

OBSTETRICS/GYNECOLOGY

Wanted: Board eligible or certified Obs/Gyn to join established physician in rapidly growing North-West CT. Gorgeous rural area close to N.Y.C. and other large urban areas. Excellent opportunity for ambitious person. Details of association can be flexible—opportunity is unique. Send resume to: CSMS, OB/GYN/PK.

PEDIATRICS

Well established pediatric practice adjacent to Hartford Hospital. Negotiable financial arrangements. Contact, John E. Cartland, Jr., M.D., 85 Jefferson St., Hartford, CT 06106.

PSYCHIATRY

Established Psychiatric practice available in southeastern Connecticut. Physician retiring. Write, CSMS, PSY/CK.

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General Surgeon. We are offering an historic New England town, top schools, ample recreation facilities, a well equipped modern hospital, and an established practice. Salary guarantee with incentives followed by partnership. Reply, CSMS, SUR/MM.

Active General Surgery Practice for sale. Located next to community hospital, in modern medical building. Attractive Litchfield County area. Contact Administrator, Box 37, Sharon, CT 06069 (364-5093).

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

ANESTHESIOLOGY

July '84. Age 32. Nat'l bds. AB elig. MD, University of Miami; Int., Rush University, Chicago; Res., University of Miami. Prefers solo, group or associate type practice. Write, U. Jain, M.D., 1500 Bay Rd., #1021, Miami Beach, FL 33139.

DERMATOLOGY

July '84. Age 30. Nat'l bds. AB elig. MD, Boston University; Int., St. Vincent's Hospital, NY; Res., Stanford Medical Center, Palo Alto, CA. Prefers group practice in a medium to large-sized community. Write, Hollis Reid, M.D., 1200 Francisco St., #5, San Francisco, CA 94123.

FAMILY PRACTICE

Jan. '84. Age 27. Presently in practice. FLEX. AB elig. MD University of Michigan; Int., University of California – Irvine; Res., University of California – Davis. Prefers Prepaid Health Group type of practice in a small to medium-sized community. Write, Susan B. Sullivan, M.D., 9911 Brady St., Redford, MI 48239.

Immediately. Age 36. FLEX. MD, Ein-shams University of Medicine, Cairo, Egypt; Int., J.C. Medical Center, Jersey City, NJ (Internal Medicine); Res., Newark/Beth-Israel Medical Center (Anesthesiology). Prefers solo, group, associate, institutional or HMO type practice in a medium-sized community. Will also do physicals for Insurance Companies. Write, Helmy W. Habek, M.D., 825 Main St., Apt. K, Belleville, NJ 07109.

INTERNAL MEDICINE

July '84. Age 26. Nat'l bds. AB elig. MD, Boston University School of Medicine; Int. and Res., Boston University Hospital; Fellowship, Mount Sinai Hospital, NYC. Prefers group or associate type practice in a small to medium-sized community. Write, David L. Oshin, M.D., 30 W. 61st St., Apt. 6D, New York, NY 10023.

May '84. Age 32. Licensed in Connecticut. AB elig. MD, Louisiana State University; Int. and Res., Danbury Hospital. Currently working in Emergency Room Service. Prefers group or associate type practice in a medium to large-sized community. Write, Phil Watsky, M.D., 101 Wilbourne #904, Lafayette, LA 70506.

July '84. Age 35. FLEX. AB elig. MD, St. George's University School of Medicine; Int. and Res., Memorial Hospital (Brown University Association). Prefers solo or associate type practice in a small to medium-sized community. Write, Brian Hennessy, M.D., 5 Chestnut St., Pawtucket, RI 02860.

April '84. Age 29. Nat'l bds. AB elig. MD, SUNY at Buffalo, NY; Int. and Res., Albany Medical College, NY. Prefers solo, group or associate type practice in a small to medium-sized community. Write, Nicholas Bertini, M.D., 663 Hudson Ave., Albany, NY 12203.

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July '84. Age 28. Nat'd bds. AB elig. MD and Int., Wayne State University, Detroit, MI; Res., St. Joseph Mercy Hospital, Ann Arbor, MI (University of Michigan affiliate). Prefers group or institutional type practice in a large-sized community preferably Hartford or New Haven. Write, Victoria D. Woods, M.D., 2124 Pauline Blvd., #208, Ann Arbor, MI 48103.

CARDIOLOGY. July '84. Age 31. MD, Government Medical College, Punjabi University, Patiala, Punjab, India; Int., Rajindra Hospital, Patiala, India; Res., Mt. Carmel Mercy Hospital, Detroit, MI; Fellowship, St. Vincent Hospital, Worcester, MA. Will look into any good opportunity and type of practice. Write, Navtej Singh Rangi, M.D., 21 Heywood St., #HC, Worcester, MA 01604.

ENDOCRINOLOGY. July '84. Age 38. Licensed in Connecticut. FLEX. AB elig. MD, Faculty of Medicine, Cairo University; Res., Mercy Hospital, Buffalo, NY; Fellowship, University of California Irvine and St. Francis Hospital and Medical Center, Hartford, CT. Desires solo, group or associate type practice in a medium to large-sized community. Write Tarek L. Haw, M.D., 1921 Asylum Avenue, Apt. 420, Hartford, CT 06105.

GASTROENTEROLOGY. Immediately available. Age 38. AB cert. MD, Karnatak Medical College, India; Int., St. John Hospital, Cleveland, OH; Res. and Fellowship, Jewish Hospital & Medical Center of Brooklyn. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Prakash V. Huded, M.D., 80-15, 41st Ave. #606, Elmhurst, NY 11373.

GASTROENTEROLOGY. Age 32. FLEX. AB elig. MD Stanley Medical College, Madras, India; Int. and Res., VA Hospital, Bronx, NY; Fellowship, Middlesex General University Hospital, Rutgers Medical School, New Brunswick, NJ. Prefers solo or associate type practice. Write, Palaniswamy Kothandaraman, M.D., 9 Lake Avenue, Apt. 5A, East Brunswick, NJ 08816.

INTERNAL MEDICINE – Continued

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PULMONARY DISEASE. July '84. Age 31. AB elig. MD, B.J. Medical College, India; Int., B.J. Medical College affiliated hospitals; Res., Helene Fuld Medical Center, Trenton, NJ; Fellowship, Brookdale Hospital Medical Center, Brooklyn, NY. Desires solo, group, associate or institutional type practice. Write, Dinesh C. Talati, M.D., 66-02 Grand Central Parkway, Apt. 1-B, Forest Hills, NY 11375.

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July '84. Age 29. Nat'l bds. AB elig. MD, University of Connecticut; Int., Hartford Hospital; Res., Boston University. Prefers solo, group, associate or institutional type practice. Write, Scott L. Dolin, M.D., 163 Strathmore Rd., Brighton, MA 02135.

July '84. Age 32. Nat'l bds. AB elig. MD, State University of NY at Buffalo; Int., Mercy Hospital, Pittsburgh, PA; Res., Eye & Ear Hospital, Pittsburgh, PA. Experienced in ECCE, Posterior and Anterior Chamber IOL's, Argon and Yag Laser for Posterior and Anterior Segment work. Prefers solo, group or associate type practice in a medium-sized community. Write, Donald L. Cohen, M.D., 5241 Gardenville Rd., Pittsburgh, PA 15236.

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ORTHOPEDIC SURGERY

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PATHOLOGY

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PSYCHIATRY

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SURGERY

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Comparative Review of Beta-Blocking Agents

ERIC A. JACKSON, PHARM.D. AND STEPHEN A. SULLMAN, B.S., PHARM.

Introduction

The release of pindolol in November, 1982 brings to six the number of beta-blockers now available for clinical use in the United States. Extensive clinical experience with these drugs has not shown any one of them to be clinically superior to the others in terms of efficacy in the treatment of a number of cardiovascular diseases (hypertension, arrhythmias, angina pectoris). However, one drug may be better than another in decreasing side effects in certain patients and in specific clinical situations. The pharmacologic and pharmacokinetic properties of the beta-blockers should be compared when attempting to evaluate the relative value of these drugs. [1-3]

This comparative review consists primarily of four tables with short discussions for each table. The six beta-blockers covered in this review include: atenolol (Tenormin^R, Stuart), metoprolol tartrate (Lopressor^R, Geigy), nadolol (Corgard^R, Squibb), pindolol (Visken^R, Sandoz), propranolol HC1 (Inderal^R, Ayerst), and timolol maleate (Blocadren^R, Merck Sharp & Dohme).

Table 1
Pharmacologic Properties

Beta-blockers are competitive inhibitors of catecholamine binding at beta-adrenergic receptor sites. These drugs decrease the effect of the agonist (catecholamine) on sensitive tissue. [4] The beta-blockers differ pharmacologically in potency, selectivity, and partial agonist activity. These differences are summarized in Table 1.

The potency of beta-blockade is determined by the ability of the drug to inhibit tachycardia produced by isoproterenol (an agonist). Using propranolol's inhibition as the baseline for comparison, pindolol and timolol are the most potent beta-blockers currently available. Atenolol, metoprolol, and nadolol are all equivalent to propranolol. [4] While differences in potency do not affect efficacy, they do help to determine therapeutically equivalent doses when switching from one beta-blocker to another. Bioavailability date (Table 2) is also needed in order to calculate equivalent doses.

Table 1
PHARMACOLOGIC PROPERTIES OF SELECTED BETA-BLOCKERS

Drug	*β-blockade Potency ratio* (propranolol = 1)*	*Cardio-selectivity*	*Partial agonist activity*
Atenolol	1.0	+**	0
Metoprolol	1.0	+**	0
Nadolol	∼1.0	0	0
Pindolol	6.0	0	+
Propranolol	1.0	0	0
Timolol	6.0	0	0

*Determined by inhibition of tachycardia produced by isoproterenol administration.

**Cardioselectivity of metoprolol and atenolol is relative—selectivity decreases as the daily dose exceeds 100 mg.

Beta-adrenergic receptors are subdivided into two distinct types: β_1 receptors located primarily in the heart and β_2 receptors in smooth muscle sites of peripheral blood vessels and bronchi. Stimulation of β_1 receptors results in lipolysis and cardiac stimulation, while β_2 receptors mediate vasodilation and bronchodilation.[5] Cardioselectivity refers to the ability to block β_1 receptors with little effect on β_2 receptors in the lungs and blood vessels. Atenolol and metoprolol are *relatively* cardioselective beta-blockers. Unfortunately, their cardioselectivity decreases as dosage is increased, even within the recommended daily dose range. [1] When used in low doses cardioselective beta-blockers *may* be preferred over nonselective beta-blockers in patients with airway obstruction or

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Table 2
PHARMACOKINETIC PROPERTIES OF CURRENTLY MARKETED BETA-BLOCKERS

Drug	*Extent of Bioavailability* (% of Dose)*	*Elim. t½ (h)*	*% Excreted Unchanged in Urine (% of dose)*	*Main Route of Elimination*	*Clinically Important Active Metabolites*
Atenolol	40-50	6-9	∿40 (po)	Renal	No
Metoprolol	30-50	3-4	∿3 (po)	Hepatic	No
Nadolol	30-35	14-24	73 (iv) 25 (po)	Renal	No
Pindolol	90	3-4	40-50 (po)	Renal & Hepatic	No
Propranolol	30	4-6	<1 (po)	Hepatic	Yes
Timolol	45	4	∿20 (po)	Renal** & Hepatic	No

*Takes into consideration oral absorption and first pass metabolism.
**Twenty percent unchanged, remainder as metabolites.

bronchospastic disease, diabetic patients prone to hypoglycemia, and patients with peripheral vascular insufficiency (Raynaud's disease).[1,2] However, it is important to remember that patients with bronchospastic disease should not receive beta-blockers unless absolutely necessary.

Another property of certain beta-blockers is partial beta-agonist activity, also known as intrinsic sympathomimetic activity (ISA). Agents possessing ISA cause a modest activation of the beta-receptor, in addition to preventing the access of catecholamines to the receptor.[1] Pindolol is the first beta-blocker with significant ISA to be marketed in the United States. Unlike the relative cardioselectivity of atenolol and metoprolol which diminishes as dosage is increased,[1] the partial agonist activity of pindolol is not lost when higher doses are used.[6]

Beta-blockers with ISA cause less slowing of heart rate at rest than propranolol, although the increments in heart rate with exercise are similarly blunted. The relative importance of pindolol's partial agonist activity, as compared with its beta-blocking effect, is greatest when sympathetic tone is low, i.e., in resting subjects.[7] It is thought that beta-blockers with ISA may be less likely to induce heart failure in susceptible patients, since they would be expected to diminish the force of contraction to a lesser extent than beta-blockers without partial agonist activity.[8] However, patients with congestive heart failure or impending heart failure rely on a high level of sympathetic activity to maintain their cardiac output. All beta-blockers are contraindicated in such patients.[7] Pindolol does not produce airway obstruction in normal subjects and appears to be better tolerated than propranolol in patients with bronchospasm.[9] However, more definitive clinical trails are necessary to define the true significance of ISA.

Clinically, beta-blockers with ISA appear to be as efficacious in the treatment of arrhythmias, angina, and hypertension as those beta-blockers lacking this property. Drugs with ISA lower blood pressure primarily by decreasing peripheral resistance as opposed to decreasing cardiac output.[7]

Tables 2 and 3

Pharmacokinetic Properties

While there are significant differences in the gastrointestinal absorption of the beta-blockers, the overall bioavailability of all of these drugs except pindolol is quite similar. The extent of bioavailability (percent of dose) is determined by the combined effects of oral absorption and metabolism prior to reaching the systemic circulation (first-pass metabolism).

The solubility characteristics of these drugs (lipid soluble vs. water soluble) influence their elimination patterns. Propranolol, which is highly lipophilic, is almost completely metabolized before excretion, while the two drugs with low lipophilicity (nadolol and atenolol) are excreted primarily unchanged in the urine.[4] Note that the column in Table 2 labeled percent excreted unchanged in the urine represents percent of administered dose, not percent of absorbed dose.

The elimination half-lives of nadolol and atenolol (low lipophilicity) are longer than the more lipophilic drugs.[4] The clinical significance of these long elimination half-lives is questionable because of a lack of a correlation between duration of pharmacologic effect and plasma half-life. The four beta-blockers with short half-lives have all been shown to be effective in treating hypertension when given once or twice a day.

The main route of elimination for atenolol, nadolol, pindolol, and timolol is renal, consequently dosage reductions for these drugs may be needed in the presence of significantly impaired kidney function. Propranolol dosage in renal failure may also have to be decreased because an active metabolite is excreted by the kidneys. Metoprolol dosage does not need to be decreased in the presence of renal failure as its main route of elimination is hepatic metabolism and there are no active metabolites.[4] In patients with hepatic insufficiency the

Table 3
CHARACTERISTICS INFLUENCING CNS PENETRATION
OF CURRENTLY MARKETED BETA-BLOCKERS

Drug	*% Protein Binding*	*Partition Coefficient (P*)*	*Lipophilicity*
Atenolol	<5	0.015	Low
Metoprolol	12	0.98	Mod.
Nadolol	25-30	0.066	Low
Pindolol	40-60	0.82	Mod.
Propranolol	>90	20.2	High
Timolol	∿10	1.16	Mod.

*Ratio of drug concentration in octanol and aqueous buffer, determined at pH 7.4 and 37 °C.

Table 4
APPROVED INDICATIONS OF BETA-BLOCKERS

Indications	*Atenolol*	*Metoprolol*	*Nadolol*	*Pindolol*	*Propranolol*	*Timolol*
Hypertension	Yes	Yes	Yes	Yes	Yes	Yes
Angina Pectoris	No	No	Yes	No	Yes	No
Arrhythmias	No	No	No	No	Yes	No
Migraine Headache	No	No	No	No	Yes	No
Post-M.I. prophylaxis	No	No	No	No	*	Yes
Others	No	No	No	No	Yes	No

*Expected to receive FDA approval in near future.

dose of metoprolol, propranolol, pindolol, and timolol may have to be decreased.

Pharmacokinetic differences between beta-blockers are important in determining equivalent doses when switching from one drug to another (along with knowledge of potency), and in determining the most appropriate drug and dose in patients with renal or hepatic disease.

Table 3
Characteristics Influencing CNS Penetration

Side effects of beta-blockers not clearly related to beta-blockade may result from their actions on the CNS (lethargy, depression, hallucination). The distribution characteristics of any drug depends upon both plasma protein binding and lipophilicity. The degree of protein binding is independent of lipophilicity. Lipophilicity seems to be more important than the degree of protein binding in influencing penetration into the CNS.

The partition coefficient in octanol and water (represented in Table 3 as P) is used to determine a drug's solubility characteristic. A high partition coefficient is associated with lipophilicity and a low coefficient with hydrophilicity. Propranolol has the highest lipophilicity and atenolol and nadolol the lowest lipophilicity (hydrophilic). Metoprolol, pindolol and timolol are moderately lipophilic. Propranolol achieves brain concentrations about 20 times higher than that of atenolol reflecting the high affinity of the brain for this lipophilic drug.[2]

The low concentration of a hydrophilic drug in the brain may possibly explain the low incidence of CNS side effects of a drug such as atenolol. Many of the CNS-related side effects noted in patients on lipophilic beta-blockers such as propranolol may disappear or markedly improve when a hydrophilic drug such as atenolol is substituted.[10]

Table 4
Approved Indications

Of interest here are the numerous approved indications of propranolol relative to the other four drugs. Also, timolol is the only beta-blocker with current approval for post-MI prophylaxis; however, propranolol and metoprolol have shown similar results in decreasing mortality in patients surviving an acute MI.[11, 12] Propranolol is expected to receive FDA approval for this indication in the near future.

Summary

While all of the currently available beta-blockers appear to be equally effective in the treatment of a number of cardiovascular disorders, knowledge of the differences in their pharmacologic and pharmacokinetic properties may aid the clinician in the selection of the most appropriate beta-blocker for a given patient. Hopefully, the information provided in this comparative review will help in promoting the rational use of this important class of drugs.

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ADDENDUM

Since this article went to press propranolol has received FDA approval for post-MI prophylaxis.

Ketoconazole

PAUL H. DEUTSCH, R.PH., M.D. AND RICHARD QUINTILIANI, M.D.

The development and availability of the antifungal agent, ketoconazole, has aroused interest among clinicians because of its wide spectrum of activity, ease of administration, and relative lack of toxicity.

Ketoconazole is an imidazole antifungal agent chemically related to clotrimazole and miconazole (Figure 1). However, it differs from these earlier agents in that it can be administered orally to treat certain fungal infections.

Mechanism of Action

Ketoconazole, like other imidazole derivatives, exerts its antifungal action by inhibiting the biosynthesis of ergosterol, the primary sterol of fungal membranes.[1] Mammalian cells do not require ergosterol for stability of their plasma membranes. The synthesis of cholesterol, the major sterol of mammalian cells, is partially inhibited by ketoconazole. However, this is usually not an important action at ordinary doses, and cholesterol is readily available in the diet.

Previous studies have found antagonism between imidazole antifungal agents and amphotericin B both *in vitro* and*in vivo.*[2,3] One study[2] suggests that *in vitro* clotrimazole and amphotericin B either compete for the same sites on the cell membrane or that the binding of clotrimazole at a different site may inhibit the subsequent binding of amphotericin B. Also, since amphotericin B exerts its action by binding to ergosterol, one would expect agents which act to inhibit ergosterol synthesis to inhibit the effect of amphotericin B. However, one experimental study[4] involving athymic nude mice found no antagonism between these agents. The authors claim that a combination of the two drugs may result in a modest therapeutic advantage over therapy with either drug alone. The combination of amphotericin B and ketoconazole should not be used together *in vivo* pending further investigation.

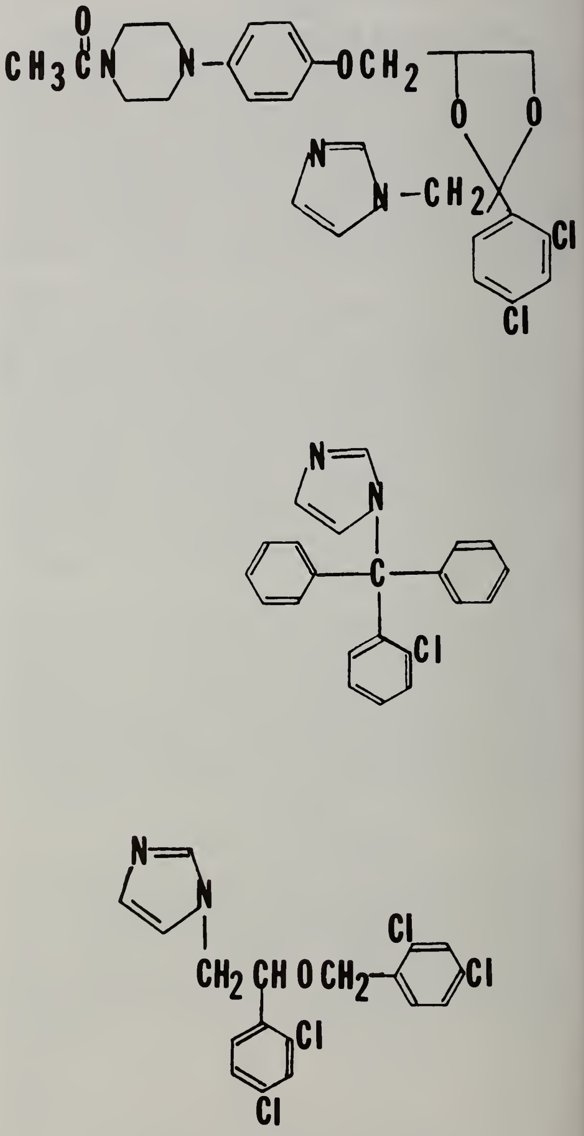

Figure 1
Chemical structures of ketoconazole (top), clotrimazole (middle), and miconazole (bottom).

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Clinical Activity

Ketoconazole has been approved by the FDA for the treatment of the following fungal infections: candidiasis, chronic mucocutaneous candidiasis, oral thrush, candiduria, coccidioidomycosis, histoplasmosis, chronomycosis, and paracoccidioidomycosis.[5] Ketoconazole has also been used for the treatment of dermatophytosis, pityriasis versicolor, and vaginal candidosis with good results. It appears to have little effect on the course of infections caused by actinomycosis, aspergillosis, and mycetoma. It may be useful for the treatment of lymphocutaneous sporotrichosis and cryptococcal infections (excluding meningitis). General guidelines for treatment are given in Tables 1, 2 and 3. However, treatment should be continued until clinical and laboratory tests indicate significant clinical response. If the clinical response is insufficient within the expected time period, the dose may need to be increased. Fungal infections are often opportunistic, reflecting a defect in the host's immune system. Suppression, but not eradication, is often the result and relapses are not uncommon.

Superficial Mycoses

Oral Thrush: In a multicenter study[6] involving 56 adult patients receiving 200 or 400mg of ketoconazole daily, remission occurred in 77% of the patients. A marked or moderate improvement was seen in an additional 7%. No change was seen in 9% of the patients. Half of the patients responded within one week after the initiation of therapy, the remaining within three weeks or less. A dose of 200mg was as effective as the 400mg dose. Controlled studies are needed to compare the efficacy and safety of ketoconazole with nystatin, the current drug of choice for the treatment of oral thrush.

Table 1

GENERAL GUIDELINES FOR TREATMENT OF SUPERFICIAL MYCOSES*

Infection	*Initial Daily Dose (mg)*	*Usual Duration of Treatment*
Oral Thrush	200 qd	1-3 weeks
Chronic mucocutaneous candidiasis	200 qd	4-12 months
Dermatophytosis	200 qd	4-8 weeks
Onychomycoses	200 qd	6-12 months
Pityriasis versicolor	200 qd	3-6 weeks
Vaginal Candidosis	200 bid	3-5 days

*The optimal dosage and duration of therapy has yet to be determined.

Table 2

GENERAL GUIDELINES FOR TREATMENT OF SYSTEMIC MYCOSES*

Infection	*Initial Daily Dose (mg)*	*Usual Duration of Treatment*
Coccidioidomycosis	400 qd	6-12 months
Paracoccidioidomycosis	400 qd	3-12 months
Histoplasmosis	400 qd	3-12 months
Chromomycosis	400 qd	6-12 months

*The optimal dosage and duration of therapy has yet to be determined. Ketoconazole is not recommended for the treatment of fungal meningitis.

Table 3

DOSAGE AND ADMINISTRATION OF KETOCONAZOLE IN CHILDREN*

Weight (kg)	*Daily Dose (mg)*
0 - 20	50
20 - 40	100
Over 40	200

*From reference.[6] Safety in children under two years of age has been documented in a limited number of cases.

Chronic Mucocutaneous Candidiasis: Ketoconazole appears to be the drug of choice for the treatment of chronic mucocutaneous candidiasis.[7] In one collaborative study[6] in which 58% of the patients had failed to respond to previous antifungal therapy, 25% of patients achieved remission, 52% showed marked improvement, and 3% were unchanged after 15 months of therapy. Half of the patients responded after four months of therapy. Increasing the daily dose did not improve the response. Prophylactic therapy is necessary to prevent recurrence of the disease. Current evidence indicates that 200mg a day is needed to maintain remission. However, one author[8] found that it was possible to prevent recurrence (followed for seven months after remission) in two patients he treated with 200mg of ketoconazole a week.

Dermatophytosis: Several studies suggest that ketoconazole may be superior to griseofulvin in the treatment of dermatophyte infections. Robertson et al[9] evaluated the efficacy of ketoconazole (200-400mg daily) in patients who had failed to respond to previous griseofulvin therapy. Clinical improvement occurred in all patients within 10-60 days (mean, 27 days). Clinical response occurred first on the trunk, then on the hands, and last on the feet. In a double-blind comparison of ketoconazole and griseofulvin, patients were treated with either 200mg of ketoconazole or 250mg of griseofulvin daily for four to eight weeks.[10] At the completion of therapy, 83% of the patients treated with ketoconazole and 32% of the patients treated with griseofulvin were considered cured by clinical and laboratory examination ($P = <.001$).

Onychomycoses: Patients with onychomycoses due to either Trychophyton or Candida species were treated with 200mg of ketoconazole daily.[11] The average duration of treatment was 7.5 months for disease due to Trychophyton species and 6.5 months for disease due to Candida species. Sixty-six percent of patients with Trychophyton infections were considered cured of their lesions, while an additional 18.5% showed improvement by 50% or more. Sixty-nine percent of patients with Candida infections were cured. An additional 11.6% showed improvement by 50% or more. Approximately 7% of patients with Trychophyton infections and 2% with Candida infections were considered therapeutic failures. The remaining patients could not be evaluated. In general, toenail infections responded more slowly than fingernail infections. In patients who had previously failed to respond to griseofulvin therapy,[9] 200-400mg of ketoconazole daily was given. All patients showed improvement after six to ten weeks of therapy.

Pityriasis Versicolor: Seventy-eight of eighty-two patients treated with 200-400mg daily of ketoconazole were considered cured of their infection by Woods lamp or direct microscopic examination.[12] Maximal therapeutic effect was seen in three to six weeks after the initiation of therapy. Patients were instructed to bathe only once daily, immediately before ingestion of the drug (the drug may reach the site of infection by excretion via the sebum). During the first two weeks of therapy, the lesions became more prominent before finally resolving in half of the patients. Intermittent administration of the drug every few days may be as effective as daily administration in clearing the lesions. A few patients have responded to single dose therapy. Prophylactic regimens to prevent recurrence need further study. Borelli suggests that 200mg once a month for three months after cure may be sufficient.

Vaginal Candidosis: Several dosage schedules have been studied to determine optimal therapy.[13, 14] Optimal response appears to occur with a dose of 200mg twice daily for five days, although there is little difference in remission and relapse rates with dosing schedules involving a total dose of 1200mg or more.[14]

Systemic Mycoses

Coccidioidomycosis: Sixty patients with coccidioidomycosis were treated with ketoconazole.[15] Their responses were evaluated in respect to the primary site of infection. Improvement (greater than 50% by measured parameters) occurred in 12 of 19 patients (63%) with chronic pulmonary infections (one cure), 20 of 23 patients (87%) with soft tissue lesions (six cured), and six of eleven patients (55%) with skeletal lesions (one cured). Infection involving soft tissues responded most rapidly (average 34 days, 200 mg once daily), followed by pulmonary infections (63 days, 400mg once daily). Overall, remission occurred in 13% of the cases, improvement in 76%, no change in 11%. Recurrence was less likely in patients treated for longer than six months. The authors recommend that therapy be continued for a minimum of six months after improvement has been documented. In patients treated with ketoconazole, 200-600mg daily for a minimum of six months, objective improvement was noted in seven of eight cases of synovitis, and three of eight cases of osteomyelitis.[16] Despite improvement, all patients had evidence of residual infection. No studies comparing ketoconazole with other antifungal agents for the treatment of coccidioidomycosis have been performed.

Paracoccidioidomycosis: Thirteen patients treated with 200mg a day of ketoconazole for three to twelve months all showed improvement in their disease.[17] Mucosal and skin lesions began to improve after two weeks of therapy, and all patients had healing of their lesions within three months. Pulmonary lesions healed (by fibrosis) in 80% in six months to one year. Although experience is limited, Cuce et al[18] consider ketoconazole to be the drug of choice for this disease. Further studies are needed to clarify the optimal dose, duration of treatment, and to compare the efficacy of ketoconazole with other antifungal agents.

Histoplasmosis: Symoens et al[19] reported that 80% of patients treated with ketoconazole showed either marked improvement or were cured of their lesions. Upper respiratory tract lesions responded the best (100%), followed by lesions in the gastrointestinal tract (87%). Thirty-nine percent showed residual pulmonary disease by x-ray.[7] However, it was not known how many of these lesions were still active. Four patients with progressive disseminated histoplasmosis were treated with ketoconazole.[20] All patients improved with resolution of symptoms, decreased liver and spleen size, weight gain, and resolution of oral ulcers when present. Decreases in serum alkaline phosphatase correlated best with clinical improvement. The authors recommend an initial dose of at least 400mg of ketoconazole daily for one year for the treatment of progressive disseminated histoplasmosis.

Systemic Candidiasis: Ninety patients[21] with candidiasis involving the urinary tract (41 patients), respiratory tract (18), blood (ten), biliary tract (nine), esophagus (seven), musculoskeletal system (three), myocardium (one), and orbit (one) were treated with 200mgm of ketoconazole once or twice daily. Overall, remission occurred in 72% of the patients with marked improvement in an additional 11%. Half of the patients responded after one week of therapy. One patient,[22] who was a known heroin abuser, with candida endocarditis received 400mg of ketoconazole daily as prophylactic therapy after valve replacement and relapse on standard antifungal therapy. She had remained well after 12 weeks on this regimen. Experience with ketoconazole for systemic candidiasis is too limited to evaluate the drug's effectiveness.[7]

Candiduria: Twenty patients with asymptomatic candiduria were treated with 200mg of ketoconazole once or twice daily. Thirteen (65%) of the patients had negative urine culture within one to two weeks. The response rate tended to be higher in males. The extent of colonization in individual patients may have a considerable bearing upon the results of treatment in view of the limited excretion of ketoconazole in the urine.[6]

Chromomycosis: Seventeen patients with chronomycosis were treated with 200-800mg of ketoconazole daily.[6] Nine of the patients (53%) showed marked improvement or clinical cure. The median time for response was around ten weeks. Increasing the daily dose of ketoconazole above 200mg did not improve the response. Considering that no completely satisfactory therapeutic agent exists for treatment of this disease, these results are encouraging. Surgical excision is presently the treatment of choice.

Sporotrichosis: Several patients with lymphocutaneous sporotrichosis have been treated with 200-400mg of ketoconazole daily.[19, 21, 32, 34] Results from patients treated for periods of three to six months varied from moderate improvement to cure.

Cryptococcus: Three patients with cryptococcal infections of the lung and joint space were treated with ketoconazole for periods of five months to one year. One patient showed moderate improvement, one marked improvement, and one patient was considered cured.[19]

Meningitis: Ketoconazole is not recommended for the treatment of fungal meningitis. Several patients have failed to respond to ketoconazole therapy.[15, 16, 23, 28, 36]

Ketoconazole was found superior to a combination of nystatin and amphotericin B for the prophylaxis of fungal infections in severely immunocompromized patients.[24] In a placebo-controlled study Brincker[25] found ketoconazole superior to placebo in reducing the incidence of clinically apparent fungal infections. The long term value of prophylactic therapy and the development of resistant fungal infections in patients receiving such therapy needs further evaluation.

Pharmacokinetics

Ketoconazole is a weak dibasic compound (pKa^1 = 6.51, pKa^2 = 2.94) which in insoluble in water, except at a pH less than 3.[26] Therefore, it requires sufficient gastric acidity for dissolution and subsequent absorption. Patients with achlorhydria or who are taking drugs which markedly reduce gastric acidity exhibit decreased absorption.[27] It is recommended that patients receiving antacids, anticholinergics, or cimetidine delay the administration of these agents at least two hours after taking ketoconazole. For patients with achlorhydria, the drug should be dissolved in an acidic solution (the manufacturer recommends 4ml of 0.2 N HCI). Since ketoconazole is lipophilic, its bioavailability is higher and more consistent when it is administered with or just before a meal.[6, 28]

Ketoconazole is well absorbed after oral administration. Peak plasma concentrations are reached in two hours after a 200mg dose, and three hours after a 400mg dose.[26]

Ketoconazole may be metabolized by the liver before it reaches the systemic circulation.[26, 28] This process is called the first-pass effect; ie, a large fraction of the absorbed dose is rapidly catabolized during the initial perfusion of the liver by portal blood from the gastrointestinal tract. As the dose is increased, this catabolic system is overloaded and more active drug is released to the circulation. This would account for disproportionate changes in peak plasma concentrations and half-life of the drug seen when small vs. large doses of the drug are given.

Levels measured in the cerebrospinal fluid have varied. Brass et al[28] found detectable concentrations of ketoconazole in patients with inflamed meninges. The average CSF concentration in patients receiving 400mg daily was 0.39ug/ml (average serum level was 4-5ug/ml although no significant association was found between serum and CSF levels at the same sampling time). Ketoconazole was not detected in the CSF of patients without active meningeal disease. Perfect et al[23] reported serum and CSF levels of 8.8ug/ml and 2.1ug/ml, respectively, five hours after a 600mg dose in a patient with cryptococcal meningitis who failed to respond to therapy. In another patient with cryptococcosis treated for four months with ketoconazole in doses up to 800mg daily, CSF levels never exceeded 0.14ug/ml, being less than 1.5% of the corresponding serum levels.[29]

Ketoconazole is 99% bound to plasma proteins, primarily to albumin.

The distribution of drugs into breast milk is primarily by passive diffusion of the lipid-soluble, non-ionized moiety. The pKa of the drug and the pH difference between the milk and plasma determines the degree of unionized drug which will be distributed between the two compartments. Since human milk is more acidic (pH - 6.6) than plasma (pH - 7.4) more unionized drug will be present in the plasma than in breast milk. Thus, the distribution of weak bases, such as ketoconazole, from the plasma to milk is favorable. In lactating beagle dogs,[29] concentrations of the drug in the milk varied from 4-12% of the corresponding plasma levels.

Approximately 0.8% of an administered dose of ketoconazole reaches the placenta, maximal fetal concentrations amount to about 0.5% of the dose.[6] Embryotoxicity, syndactylia, oligodactylia, and dystocia have been noted in rats given ketoconazole in doses higher than that recommended for human consumption.

Plasma elimination is biphasic. The initial phase represents the distribution of the drug between the blood and other body fluids and tissues, while the second phase represents distribution of the drug from the tissues and fluids back to blood and subsequent elimination from the body. The half-life (t½ B) of ketoconazole is 6.5, 8.1, and 9.6 hours after a dose of 100, 200, and 400mg respectively.

Ketoconazole is extensively metabolized by the hepatic microsomal-oxidase system. The major route of elimination is through the bile. About 13% of the drug is excreted in the urine, 2-4% of which is unchanged drug.[6] It appears that patients with renal disease do not require a modification of the dose, while patients with liver disease may.[28] The amount of drug removed by dialysis is negligible.

Side Effects

The overall incidence of adverse reactions in patients taking ketoconazole is 10%, most of these not being serious.[6, 19] It has been well tolerated, treatment being discontinued because of side effects in only 1% of patients.

The most frequently reported side effect is nausea and/or vomiting, occurring in approximately 3% of patients. It is a dose related effect, usually associated with doses of 400mg or more.[9, 19, 32] Administration of the drug with meals usually decreases the incidence of these effects. The symptoms have disappeared in a number of cases without any change in therapy. Other commonly reported side effects include: abdominal pain, constipation, diarrhea, pruritus, rash, headache, dizziness, somnolence, fever, and chills.

Gynecomastia has been reported in a small number of male patients.[15, 26, 30-32] It may be due to either a direct effect of the drug on breast tissue[30] or result from suppression of serum testosterone levels.[31, 32] Therapeutic concentrations of ketoconazole have been shown to block testosterone synthesis in a dose-dependent manner.[31] One patient treated with 1200mg a day of ketoconazole developed azospermia.[33] Oligospermia persisted for three weeks after the discontinuation of therapy. Ketoconazole has recently been shown to blunt the response of cortisol to adrenocorticotropin hormone.[32] *In vivo,* augmentation of ACTH release, increased uptake of cholesterol from the circulation, along with recovery from the blockage four to sixteen hours after the administered dose may compensate for this action. At the currently recommended doses, the drug is well tolerated. However, patients receiving ketoconazole in high doses or more frequently than once daily may have decreased adrenal reserve and should be watched for the signs and symptoms of hypoadrenalism.

Elevations of serum transaminases have been noted in approximately 10% of patients.[31] The increases are usually mild (within twice the upper limit of normal) and not associated with signs or symptoms of liver dysfunction. They often return to normal despite the continuation of therapy.[34, 35] The mechanism underlying this adaptation is unknown. The increases most often appear between 10-160 days of therapy; the median being 14 days. Twenty-four cases of ketoconazole-induced hepatitis have been reported to date.[35] The hepatotoxicity appears to be a non dose-related, idiosyncratic reaction. In one case, a 68-year-old woman treated with ketoconazole for 14 weeks developed signs and symptoms of hepatitis associated with elevations of transaminases and bilirubin.[36] Liver biopsy confirmed the diagnosis. Rechallenge with ketoconazole produced similar results. In one patient who developed hepatitis, jaundice resolved and liver enzymes returned to normal despite continued therapy.[37] Three cases of fatal massive hepatic necrosis have been reported[35] despite the discontinuation of therapy. The duration of ketoconazole treatment in cases reported by the FDA ranged from 11-110 days with a median duration of 56 days. Daily doses ranged from 100-400mg with a mode of 200mg daily. Estimates of hepatotoxicity range from 1:7500 to 1:15,000 and patients with ketoconazole hepatotoxicity may be asymptomatic. Both centrilobular necrosis (with and without cholestasis) and periportal hepatitis have been noted on biopsy.[36] Monitoring to detect evidence of hepatotoxicity should include baseline liver function tests such as SGGT, SGOT, alkaline-phosphatase, and bilirubin. Testing at two and four weeks of therapy, with monthly testing thereafter, should detect most cases of impending hepatotoxicity. If liver function tests become significantly elevated or if other signs and symptoms of hepatic dysfunction occur, ketoconazole should be discontinued.

Other side effects include: photophobia, insomnia, nervousness, increase in appetite, hypertension, arthralgias, myalgias, and alopecia.[6, 29] The drug appears to have no effect on renal function.

Drug Interactions

As noted previously, drugs which inhibit gastric acid secretion decrease the absorption of ketoconazole, and ketoconazole probably antagonizes the action of amphotericin B *in vivo.* There appears to be no interaction between ketoconazole and flucytosine, additive or otherwise. There also appears to be no interaction with oral hypoglycemic agents. While Brass et al[28] found no interaction between ketoconazole and coumadin, it appears that rifampin and phenytoin enhance the metabolism of ketoconazole, probably by the induction of hepatic microsomal enzymes. Other drugs capable of this action may produce similar results. However, the clinical significance of this interaction is not yet known.

Conclusion

Ketoconazole is a relatively new antifungal agent with a wide spectrum of activity. It has the advantage of oral administration and is well tolerated by most patients. However, ketoconazole is not without adverse effects. Most of the adverse reactions are mild and often disappear even with continued therapy. Considering its wide use, serious toxicity with ketoconazole is rare.

Ketoconazole's exact place in therapy is yet to be determined. Because of the long response time needed for ketoconazole, amphotericin B will probably remain the drug of choice for treatment of systemic fungal infections. It is probably the drug of choice for treatment of chronic mucocutaneous candidiasis. It is also useful for the treatment of both oral and vaginal candidiasis, and pityriasis versicolor. With more experience, it may replace griseofulvin as the oral agent of choice for the treatment of dermatophyte infections, including onychomycosis.

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Pasteurella Multocida Septic Arthritis

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ABSTRACT—A 68-year-old woman with chronic rheumatoid arthritis treated with corticosteroids was scratched by her pet cat. Fulminant Pasteurella multocida septicemia developed complicated by shock, disseminated intravascular coagulation, the adult respiratory distress syndrome, and bilateral prosthetic knee infection. Treatment with high dose penicillin was curative without loss of the prostheses. Pasteurella multocida septicemia and septic arthritis resulting from animal induced wounds are reviewed.

Pasteurella multocida, a gram negative coccobacillus with distinctive penicillin sensitivity, is primarily an animal pathogen which causes fowl cholera and hemorrhagic septicemia in livestock.[1] A large reservoir of the

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organism exists as upper respiratory and gastrointestinal commensals in healthy domestic animals, particularly dogs and cats. A broad spectrum of human zoonotic infections have also been reported.[1] Infection in humans may follow animal bites or scratches, casual animal contact, or no apparent animal contact in 5-15% of cases.[2] Transmission to man most commonly results from percutaneous inoculation.[3] The ensuing soft tissue infection is characterized by rapid development of localized edema and suppuration. Complications include tissue sloughing, abscess formation, tenosynovitis and osteomyelitis, but bacteremia and metastatic infection are rarely reported.[3] We report a patient in whom cat scratch induced P. multocida infection led to bacteremia, disseminated intravascular coagulation, and the adult respiratory distress syndrome.

Case Report

A 68-year-old retired bank secretary with classical rheumatoid arthritis of ten years duration was brought to the hospital after falling at home. Four days prior to admission, the patient was scratched by her pet cat on the inner aspect of her left thigh. The scratch site became necrotic, and swelling and erythema of the leg developed.

The patient's medications were prednisone 10 mg daily, which she had taken for ten years, and aspirin 4 grams daily. She had been treated in the past with cyclophosphamide, chlorambucil, plaquenil and penicillamine, but was not receiving any of these medications. Multiple surgical procedures had been performed including reconstructive hand surgery, a C1-C2 cervical fusion, and bilateral total knee joint replacements.

On admission, the blood pressure was 78/54 mm Hg. The temperature was 103.6 °F and the pulse 114. On the inner aspect of the left thigh there was a 4 cm linear wound rimmed by a half inch of necrotic tissue. The left leg was diffusely swollen, and both knees had easily palpable effusions. There were extensive deformities of rheumatoid arthritis involving the hands, wrists, shoulders and feet. No wound was evident on the right leg.

The white cell count was 1300 with 8 percent neutrophils, 72 percent bands, 2 percent metamyelocytes, 16 percent lymphocytes, and 2 percent monocytes. The platelet count was 230,000 but fell to 110,000 48 hours after admission. The partial thromboplastin time increased from 35.4 to 48 seconds. Fibrin split products were elevated at greater than 40 ug/ml, and microangiopathic changes were present on the peripheral blood smear. A chest X-ray showed diffuse patchy alveolar densities, and a blood gas on room air was pH 7.47, PCO_2 25 mm Hg and PO_2 50 mm Hg. The pulmonary capillary wedge pressure was 13 mm Hg.

Both knees were aspirated. Synovial fluid from the right knee revealed 70,500 red cells per cu mm and 124,000 white cells per cu mm with 96 percent neutrophils, 1 percent lymphocytes, and 3 percent tissue cells. The synovial fluid glucose was 13 mg % with a simultaneous serum glucose of 100 mg %. Gram stain of the fluid demonstrated numerous small, pleomorphic, gram negative coccobacilli. Synovial fluid analysis and gram stain from the left knee were similar.

The patient was treated with intravenous penicillin, oxacillin and gentamicin. The blood pressure fell to 60 mm Hg. Dopamine and high dose corticosteroids were added. On the third hospital day, P. multocida, sensitive to penicillin, was reported to be growing from the scratch site, both synovial fluids, and all four blood cultures obtained on admission. All antibiotics except penicillin were discontinued. Open drainage with irrigation of both knees was performed.

On the tenth hospital day, reaspiration of the left knee produced sterile synovial fluid. No loosening of the joint prostheses was noted by x-ray. The patient received two weeks of intravenous penicillin G 12 million units/day, followed by a four week course of oral penicillin. In-hospital physical therapy was necessary for one month. At the time of discharge, there was good functional recovery of both knees. She was well in follow-up one year later.

We believe this is the first reported case of bacteremic P. multocida wound infection complicated by disseminated intravascular coagulation, the adult respiratory distress syndrome, and bilateral prosthetic knee infection. Pasteurella multocida wound infection is estimated to complicate 7-29% of dog and cat bites and scratches.[3,4] In contrast, only 11 cases of P. multocida bacteremia following animal induced trauma have been reported.[4-14] In only four of these cases, was the organism recovered from both wound and blood cultures.[9-11,14] Severe underlying disease was frequently present in bacteremic patients. Of the 11 cases with positive blood cultures, five had alcoholic or postnecrotic cirrhosis,[5,7,8,10,11] and one had rheumatoid arthritis treated with corticosteroids.[6] Two patients were pregnant[12,13] and in the remaining three cases, insufficient clinical information was provided.[4,9,14] Factors predisposing our patient to systemic infection include rheumatoid arthritis[15-18] and chronic corticosteroid therapy.[19] Although neutropenia was present on admission, the white cell count returned to 6,700 within 48 hours of admission suggesting that the initial neutropenia was a result rather than a cause of overwhelming infection.

Disseminated intravascular coagulation has not previously been documented in human bacteremic P. multocida wound infection. Normann et al, reported the development of severe thrombocytopenia during P. multocida sepsis.[11] This occurred in association with chronic alcoholism and fatal hepatic failure, and cannot be ascribed to P. multocida septicemia alone. Myers et al reported a rapidly fatal "generalized Schwartzman reaction" presumed to result from P. multocida bacteremia which occurred 60 hours after a dog bite, but bacteriologic confirmation was lacking.[20] In our patient, disseminated intravascular coagulation, manifested by acute thrombocytopenia, partial thromboplastin time prolongation, elevated fibrin split products and microangiopathic hemolytic anemia, is best attributed to bacteremia alone. The rarity of disseminated intravascular coagulation in human Pasteurella infection is in contrast to septicemia in livestock in which extensive visceral petechiae and hemorrhage are common.[21]

The adult respiratory distress syndrome has not been reported in bacteremic P. multocida wound infection. In this patient, hypoxemia and diffuse alveolar infiltrates occurred with a normal pulmonary capillary wedge pressure. The prompt resolution of these radiographic and physiologic abnormalities suggest that the syndrome had occurred.

Fourteen previously reported cases of P. multocida septic arthritis have recently been reviewed.[22] A striking association between P. multocida joint infection and chronic rheumatoid arthritis was noted. Seven of the 14 patients had rheumatoid arthritis, and five of seven were receiving corticosteroids. Prosthetic knee joints were infected in four cases. Antecedent cat scratches or bites were reported in nine of 14 cases. P. multocida joint infection in our patient reinforces this identified clinical pattern. Although no specific impairment in immunity to P. multocida infection has been demonstrated in patients with rheumatoid arthritis, a general decrease in host immune responsiveness to infection has long been postulated.[23, 24] Immune defects reported in patients with rheumatoid arthritis include abnormalities of humoral immunity,[15] synovial fluid complement production,[16] and white cell chemotaxis [17] and phagocytosis.[18] In addition, prosthetic joint surgery disrupts the normal mechanical barrier to joint infection. The individual importance of these factors in predisposing patients with rheumatoid arthritis to bacterial infection in general, and more specifically with P. multocida, remains uncertain.

Bacteremia is infrequently documented in P. multocida septic arthritis. Therefore, it is postulated that joint infection usually results from contiguous spread of soft tissue infection.[25] In our patient, the presence of bacteremia, bilateral prosthetic knee infection, and a solitary primary infection site on the left thigh signifies that bacteremic seeding of the joint space occurred.

The usual outcome in staphylococcal and most gram negative prosthetic joint infections is unfavorable.[26] For these infections, sacrifice of the prostheses is usually necessary for joint sterilization. Our success with antibiotic therapy and drainage alone, combined with the success of conservative therapy in four previously reported cases of P. multocida prosthetic arthritis, indicates that joint sterilization without prostheses removal is achievable.[25, 27-29]

The potential consequences of animal bites or scratches in hosts compromised by chronic liver disease or rheumatoid arthritis must be recognized by physicians caring for these patients. Certainly, antibiotic prophylaxis of dog or cat induced wounds with penicillin is justified in these predisposed patients. Despite the favorable outcome in our patient, it must be recognized that domestic animals are a source of P. multocida infection which can be lethal in susceptible hosts.

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Evolving Diagnostic Role of Nuclear Medicine

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ABSTRACT—To examine the changing role of Nuclear Medicine, we analyzed the first 200 procedures carried out at University (Dempsey) Hospital in 1975 and compared them with the initial 200 studies in 1983. Several procedures have decreased in use, the most marked being the fall in number of brain scans (from 47 to zero) and thyroid uptake examinations (from 23 to 3). Reasons for these declines are discussed. At the other extreme, several procedures have increased in use. These include cardiac examinations (from 2 to 63), bone densitometry studies (from zero to 17), and both bone and radiogallium scans. The more physiologic, and computer assisted studies, have assumed a greater role in Nuclear Medicine.

The diagnostic specialties are in a period of evolution, with both the studies performed and the methods of carrying them out under revision. To examine the changing role of Nuclear Medicine, we studied the first 200 procedures carried out at University (Dempsey) Hospital at the University of Connecticut Health Center, during 1975 and in 1983.

Methods

The daily record of patients seen in Nuclear Medicine was examined. The first 200 procedures carried out in 1975 were tabulated. This was repeated for the first 200 procedures in 1983. Some patients had more than 1 procedure carried out, and hence, 200 procedures represent less than 200 patients.

Results and Discussion

The results are tabulated in Table 1. The Table is arranged to show (at the top) 4 procedures which increased in use in 1983 as compared with 1975. The bottom 6 procedures in the Table all decreased in use in 1983 as compared with eight years previously. We will initially discuss the procedures which had lesser use in 1983 than in 1975. The most apparent decline was in the number of brain scans (from 47 to zero). This coincided with the availability of computerized tomography (CT) studies which provided better anatomic definition of the intracranial contents. It is of note that, with the introduction of newer radiopharmaceuticals which cross the physiologic blood-brain-barrier (such as the iodo-amphetamines), brain scans have begun to make a reappearance at several centers.[1] Computer technology has played a major role in this resurgence.

Table 1

	1975	*1983*
Cardiac Studies	2	63
Bone Scans	22	41
Bone Densitometry	0	17
Radiogallium	2	12
Brain Scans	47	0
Liver Scans	37	22
Lung Scans	21	9
Thyroid Uptake	23	3
Thyroid Scans	23	12
Other, such as G.I., renal	23	21

The first 200 procedures carried out in Nuclear Medicine at University (Dempsey) Hospital in 1975 and 1983. The top 4 procedures increased in use, while the bottom 6 decreased in utilization.

Liver scans decreased from 37 to 22, out of the first 200 procedures. This was likely due to the availability of ultrasound examination, and its use as a nonionizing technique for evaluating the liver and biliary tract in selected cases. Where the question is one of function, however, the liver scan remains the procedure of choice. Perfusion lung scans also fell (from 21 to 9). There has been growing sophistication in the ordering of lung scans, with utilization of chest X-rays, blood gases, and often Doppler examination of the legs, before a lung scan is ordered.

There was also a profound change in the use of radiotracers to evaluate the thyroid. The number of thyroid uptake studies decreased from 23 to 3. This may reflect the wide use of blood studies, (T3, T4, TSH and so on) to evaluate thyroid functional status. In 1983, radioiodide uptake examinations are usually restricted to cases where

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the blood values give equivocal or conflicting results, or the uptake values are specifically needed to correlate with imaging data on a nodule or for calculating a therapeutic dose in treatment of hyperthyroidism. Thyroid scans also decreased in number in 1983, as compared with 1975. The availability of ultrasound to examine thyroid nodules, and of CT to explore substernal masses, may have been responsible.

Four procedures markedly increased in use in 1983 versus 1975: cardiac studies, bone scans, bone densitometry, and radiogallium examinations. The most dramatic was the increase in cardiac studies from 2 to 63 out of the first 200 procedures. This reflects the wide use of radiothallium examinations of the myocardium, Tc-99m-pyrophosphate images of the heart when the diagnosis of myocardial infarction is suspected but not confirmed by other techniques, and of gated cardiac blood pool studies for inferring wall motion at rest and with exercise.

The coupling of radionuclide studies of the heart with computer technology has permitted the evaluation of function throughout the cardiac cycle, both by means of gated collection and by beat to beat monitoring. These advances have led to the quantification of cardiac function through the generation of ventricular ejection fractions and filling rates. By thus defining a numerical baseline, the effects of drug therapy, surgery, or simply the passage of time can be evaluated.

While the emergence of NMR and digital subtraction angiography herald new horizons in the field of diagnostic cardiology, the nuclear medicine techniques should remain principal tools in the evaluation of the heart, particularly as new radiopharmaceuticals, more appropriate to the study of cardiac metabolism, are developed.[2]

Next to the cardiac examinations, bone scans are the most commonly performed studies in Nuclear Medicine. The passage of time has only confirmed the great sensitivity (but lack of specificity) of the Tc-99m-phosphate bone scans. In the search for early osteomyelitis, stress fractures, and small bone tumors, a bone scan remains the procedure of choice. Frequently lesions can be identified before there is X-ray evidence of disease. Often, bone scans are coupled with radiogallium studies, in an effort to find out if an infection is entirely in soft tissue or if it has involved the nearby bone.[3] Radiogallium studies have increased in number not only because of their use in detecting sites of inflammation, but also because of the role they play in staging and following tumors.[4]

The bone densitometry study was not offered as a routine clinical procedure in 1975. It has been widely accepted as a useful tool in evaluating the extent of osteoporosis (and effects of treatment), as well as evolving osteoporosis prevention programs.[5] Therefore, in 1983 bone densitometry is a well utilized procedure in Nuclear Medicine.

Throughout its development, the field of Nuclear Medicine has concentrated on organ function rather than anatomy. It is not surprising, then, that the more physiologic studies have increased in use over the past several years. For the most part, this increase has been realized in the field of cardiovascular nuclear medicine. However, with the synthesis of additional radiotracers and the use of new technologies, similar "booms" should be realized in the study of other organ systems. The use of positron emitting radiopharmaceuticals in the evaluation of brain metabolism and of monoclonal antibodies in tumor localization are but two examples of the many directions in which the field may develop. The study of organ physiology, of changing function over time, will remain the unifying theme.[6]

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Important Advances in Clinical Medicine

Epitomes of Progress—Nuclear Medicine

The Scientific Board of the California Medical Association presents the following inventory of items of progress in nuclear medicine. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in nuclear medicine that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Nuclear Medicine of the California Medical Association and the summaries were prepared under its direction.

The Role of Nuclear and Ultrasonic Thyroid Imaging

The management of thyroid nodules is troublesome because of the low but significant incidence of thyroid cancer in them and because there is not always a clear advantage in the risk of a definitive diagnosis by means of a surgical procedure versus the risk of overlooking a malignancy. An unnecessary operation can be obviated by using nonsurgical diagnostic procedures to identify those cases wherein the likelihood of malignancy is low. Noninvasive radionuclide scintigraphy and ultrasonography are almost universally available and can aid in such differentiation.

Thyroid scintigraphy identifies the 20% to 25% of thyroid nodules that are of equal or greater function than adjacent healthy thyroid. These nodules have such a low incidence of malignancy that a surgical procedure is not indicated. A solitary inactive nodule has a 10% to 30% chance of being malignant. A palpable nodule and scan must be correlated at the time of scanning to detect the nodule and accurately identify its activity. Sodium iodide I 123 and sodium pertechnetate Tc 99m are presently the radionuclides of choice.

Diagnostic ultrasound identifies the 10% to 15% of nodules that are purely cystic. These are rarely malignant. High-resolution real-time ultrasound has a greater ability to differentiate purely cystic from mixed but predominantly cystic nodules.

Because a radionuclide study has the potential to identify a larger population that does not need surgical intervention, it should be the imaging procedure of choice unless there is a contraindication to the small amount of radiation exposure. The remaining population (those with cold nodules) can be further evaluated by the use of ultrasound, thereby reducing the need for invasive procedures—that is, needle biopsy or surgical procedure or both—by 25% to 35%.

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Assessment of Liver Lesions Using Single-Photon Emission Computed Tomography

Conventional liver scintigraphy has been used extensively for the evaluation of focal and diffuse hepatic disease. The procedure is safe, accurate, very reproducible and widely available; overall accuracy for focal liver disease is about 80% in most published series. The technique is somewhat limited, however, by the

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relative lack of resolution of most defects less than 2 cm in diameter, especially deeper within the liver. Computed tomography (CT) and ultrasound typically can resolve 1-cm hepatic lesions and are most accurate nearer the center of the liver where conventional nuclear imaging is least sensitive.

Single-photon emission CT is a new technique available for liver imaging. The method requires a special γ-camera with a yoke configuration that allows the camera crystal to rotate around a patient and collect data from either a 180 degree or a 360 degree angle. A computer collects and stores the data, and images are formatted into transverse sections in a manner analogous to transmission CT. The conventional radiopharmaceuticals, such as technetium Tc 99m sulfur colloid, are used; however, the potential for imaging in a transaxial tomographic format with other tracers such as blood flow agents or tumor-specific antibodies is being actively investigated.

It is claimed that single-photon emission CT is 92% accurate in detecting focal liver lesions compared with 82% for conventional planar imaging. It is possible that this technique will detect over half the lesions between 1 and 2 cm in diameter, which conventional scintigrams rarely detect. Studies in Sweden by Lassen and coworkers suggest that its accuracy should be comparable to transmission CT, yet it should be a less expensive procedure and one in which injection of contrast material is not necessary.

Present limitations of single-photon emission CT in the liver include possible artifacts created by imperfect camera motion or computer algorithm. Interpretation of liver images produced by this method requires a working knowledge of cross-sectional anatomy and care must be expressed to avoid misinterpreting a normal portal or fissural structure as a pathologic lesion.

Single-photon emission CT will significantly add to the accuracy of nuclear liver imaging, and many lesions that might have been missed will be clearly seen.

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Radionuclide Determination of Brain Death

The decision to discontinue life-support measures in a patient suspected of having brain death demands utmost certainty and is one laden with moral, legal and financial considerations.

A brain death diagnosis is first suspected by findings on physical examination and further supported, or not supported, by results of (often serial) electroencephalography. There still may be uncertainty. Additional confirmation is often needed or desired, particularly when hypothermia or extreme sedation is present, or when the patient is a child.

Radionuclide cerebral blood flow studies are highly specific and quite sensitive in diagnosing brain death. The pathophysiology is the same as in cases of absent cerebral blood flow by contrast angiography in which intracranial pressure (due to ischemic cerebral edema) exceeds intracranial systolic blood pressure resolution.

In our experience (107 patients), specificity is very high (all who lived had negative studies) as is sensitivity (up to 85%), depending on the time of scan in relationship to actual brain death. In the literature and in our experience there are no reports of survival in patients with absent cerebral blood flow (positive predictive value of 100%). The study can easily be done at the bedside with a mobile camera using a bolus intravenous injection of technetium 99m. It is a highly reliable aid in the evaluation of brain death.

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Radionuclide Detection of Acute Lower Gastrointestinal Tract Bleeding Site

Identifying and locating active lower gastrointestinal tract hemorrhage is a serious clinical problem, particularly when surgical intervention in necessary. In many institutions, radionuclide imaging studies have become firmly established as the principal method for locating the bleeding site. These rapid and noninvasive scintigraphic techniques have largely supplanted angiography because they have proved nearly twice as sensitive for detecting bleeding sites. Bleeding sites in patients with intermittent bleeding and in those with bleeding rates below 0.5 ml per minute often cannot be detected by angiography. When the study does detect a bleeding site, contrast angiography can be directed to evaluate a specific region of the gastrointestinal tract.

The nuclear imaging studies involve intravenous administration of a radiopharmaceutical agent that remains in the circulation long enough to allow scintigraphic visualization of extravasation at the site of active bleeding.

The technique involves labeling a patient's own erythrocytes with technetium 99m by a simple and rapid modification of the standard in vivo method commonly used for gated cardiac scintigraphy. The long retention time of labeled erythrocytes in the circulation allows prolonged sequential scintillation camera imaging, which can accurately diagnose the site of hemorrhage even in intermittent bleeders. Computer acquisition of sequential one-minute images during the first 60 to 90 minutes after administration of the labeled cells allows playback in a movie format that enhances localization. These dynamic displays show that extravasation is commonly intermittent even in patients who have massive acute hemorrhage.

If no bleeding site is found within 90 minutes, hourly images for up to 24 hours may be helpful to identify intermittent bleeding. In patients with positive delayed views, a new series of sequential images may sometimes show continued extravasation at the true bleeding focus.

The ^{99m}Tc erythrocyte study is safe and has no contraindications. The radiation dose is small, particularly when compared with that for angiography. It has high patient acceptability and can be done at the bedside with a mobile scintillation camera when a patient is too ill to move. It is the study of choice in patients requiring transfusion for acute hematochezia or melena when the site of hemorrhage is not clinically obvious.

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Nuclear Magnetic Resonance Imaging

Clinical trials carried out over the past three years have validated the clinical use of nuclear magnetic resonance (NMR) imaging. Some of the advantages of NMR over existing imaging modalities include intrinsically high soft tissue contrast resolution, the ability to image in any plane with equivalent spatial resolution in all planes and the capability to delineate flowing blood without contrast material. It is entirely noninvasive, uses no ionizing radiation and has shown no adverse biologic effect. The typical initial cost of a nuclear magnetic resonance unit is between $800,000 and $1.5 million (excluding installation), compared with $600,000 to $1 million for a computed tomography (CT) system.

Clinical NMR systems produce images dependent on the magnetic properties of the hydrogen nucleus (proton). A patient is placed in a strong magnetic field and exposed to low energy (radio frequency) radiation, some of which is absorbed by protons aligned in the magnetic field. As the protons subsequently release the energy absorbed, the signal produced is detected as induced electrical currents in a receiver coil, which are processed by computer and displayed as transaxial, coronal or sagittal images.

Nuclear magnetic resonance imaging of the central nervous system has received considerable attention. There is very little NMR signal from the skull, allowing the surface of the adjacent brain to be clearly seen. This is particularly useful for imaging the posterior fossa where CT signals from the bone may cause artifactual image streaking. Brain scans using this technique show superior soft tissue contrast to that of CT and have been used to identify early lesions of multiple sclerosis in patients with normal findings on CT scans.

Nuclear magnetic resonance has also proved useful in diagnosing cardiovascular disease. Blood flowing at normal velocities generates little or no NMR signal. This results in a high natural contrast between the lumen and the walls of blood vessels, without the use of intravenous contrast agents. Thus NMR imaging is useful in defining vascular pathology and, in particular, atherosclerotic lesions. Using cardiac gating techniques, excellent images of the heart have been produced allowing visualization of congenital defects, mural thrombi and valvular disease. It appears that NMR cardiac imaging will have great value as a noninvasive means of detecting, locating and quantifying myocardial infarcts.

In the mediastinum, nuclear magnetic resonance has an advantage over CT in clearly distinguishing between blood vessels and masses.

Abdominal NMR images have excellent soft tissue resolution and clearly show the major intra-abdominal, retroperitoneal and pelvic organs. NMR images of the abdomen (without contrast administration) are comparable with contrast-enhanced CT images, but the precise role of abdominal NMR imaging vis-à-vis CT scanning remains to be futher investigated.

Nuclear magnetic resonance images contain information that is fundamentally different from the anatomic images from CT and ultrasound, and may form a basis for visualizing chemical and physiologic processes at the cellular level. Exploring this potential to detect and monitor the metabolic and pathophysiologic features of tissues in vivo is the current challenge to NMR research.

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Noninvasive Evaluation of Obstructive Versus Nonobstructive Uropathy

The differential diagnosis of hydronephrosis includes complete or partial obstruction to the transit of urine from the renal pelvis to the bladder, the sequelae of an old obstructive uropathy that has resolved and back pressure atrophy from vesicoureteral reflux, as well as various other inflammatory, neurogenic and congenital conditions. An acute obstruction can generally be diagnosed by doing a standard urogram using contrast material administered intravenously. A partial obstruction will eventually compromise renal function and yet may be resolved with appropriate surgical intervention. The "gold standard" for diagnosing a partial obstruction is the Whitaker test. Unfortunately, this is a fairly invasive test because it involves a percutaneous nephrostomy and placement of a Foley catheter in the bladder.

A noninvasive alternative to the Whitaker test is the furosemide (Lasix) renogram. This study is done simply as an adjunct to a standard technetium 99m-labeled DTPA (pentetic acid) radionuclide renal scan. Furosemide (0.05 to 1.0 mg per kg of body weight) is administered intravenously ten minutes after administration of DTPA. Data are accumulated on a computer for 25 to 30 minutes. Activity in the region of interest, chosen to include the kidney and its dilated collecting system, is then recorded by computer-generated curves as a function of time. If the collecting system is dilated but not obstructed, at least 50% of the activity will wash out from the collecting system by 15 minutes after intravenous administration of the furosemide. This study is relatively noninvasive and provides results that correlate well with those of the Whitaker test.

If enough renal parenchymal disease is present to limit the ability of the kidney to increase its urine flow in response to diuretics, the furosemide renogram could be falsely positive for partial obstruction and this constitutes the major limitation of the technique. In the presence of dilated collecting system(s), by expanding the study to a furosemide renogram it will be possible to differentiate obstructive from nonobstructive uropathy. In most cases this will obviate the need for a confirmatory Whitaker test.

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Indium 111-Labeled Leukocyte Scanning

Leukocyte scanning using indium 111 is now established as a valuable technique for detecting acute inflammatory processes. Accurate identification and noninvasive localization of abdominal and occult abscesses are the primary indications for doing this study. It has been proved conclusively that the ^{111}In-labeled leukocytes retain their viability and function while concentrating avidly in areas of abscess and inflammation. The labeling technique is simple and efficient and can be incorporated into most nuclear medicine departments. Both autologous and heterologous cells have been used successfully. The radiolabeled leukocytes are not excreted through the bowel or kidneys, which offers a significant advantage over gallium 67 scanning. The study is generally completed within 24 hours, and large series consistently report sensitivities, specificities and accuracies greater than 90%. The ^{111}In-labeled leukocyte scan is most valuable in a patient suspected of harboring an abscess or an acute inflammatory process without focal signs or symptoms. A negative result is strong evidence against the presence of a significant inflammatory process, while a positive result can expedite diagnosis and therapy.

The areas of greatest clinical use thus far include suspected abdominal abscesses without focal signs to indicate their location, postoperative patients, occult abscesses outside the abdomen, inflammatory bowel disease and bowel infarction. Conditions in which the leukocyte scan has proved to be less useful include pyelonephritis, bone and joint disorders (with the possible exception of acute osteomyelitis), bacterial endocarditis and fungal, parasitic and chronic infections. Success with ^{111}In-labeled leukocytes has stimulated research to evaluate their possible use in interstitial lung disease, rheumatic diseases and vascular infections.

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Hepatobiliary Scintigraphy in the Diagnosis of Acute Cholecystitis

Within the past few years a new class of technetium 99m-labeled radiopharmaceuticals has evolved and revolutionized the diagnostic examination of patients who may have acute cholecystitis. Loosely referred to as "HIDA" (the US Pharmacopeial Covention code designation for lidofenin), these compounds have become the standard for hepatobiliary imaging. Of the HIDA compounds, diethyl-iminodiacetic (IDA) and diisopropyl-IDA have been found most satisfactory because of their comparatively better pharmacokinetics and decreased fractional renal excretion.

Patients appropriately selected for HIDA scans are those suspected of having acute cholecystitis because of typical signs and symptoms of the disorder, including right upper quadrant abdominal pain, fever, leukocytosis and so forth. After a negative history of cholecystectomy is obtained and the patient has fasted for two hours, HIDA is injected and images taken serially with a scintillation camera for up to two hours if necessary. A normal gallbladder will appear 30 minutes to an hour later. If the gallbladder does not appear, cystic duct obstruction and associated cholecystitis are inferred. From reported series (including more than 1,000 patients) the sensitivity and specificity in this study exceed 95% even with serum total bilirubin levels of up to 4 mg per dl.

Certain cautions are advisable in inferring cholecystitis from HIDA scans. A loss in specificity, which may be considerable, can occur under some circumstances. For instance, the test has been found to be undependable in poorly nourished patients, especially in those who have alcoholism, those persons subjected to fasting of more than one day's duration (such as patients receiving long-term intravenous hyperalimentation) and in patients with total serum bilirubin levels of greater than 4 mg per dl.

A comparison between ultrasonography and HIDA scans in diagnosing acute cholecystitis has led to animated discussions, but with the above cautions, a substantial majority of experts agree that HIDA scans are superior to ultrasonography in spite of an approximate 20% cost savings of the latter. This is because ultrasonographic characteristics of acute cholecystitis are nonspecific—that is, not all patients with gallstones have acute cholecystitis; also, the cystic duct may be blocked without stones identified in the gallbladder by ultrasonography. Additionally, ultrasound studies cannot be technically interpreted in some cases (for instance, gallbladder not identified, overlying gas or dressing precludes ultrasonography). In conclusion, HIDA scans can be recommended as the single test of choice in objectively documenting the presence of acute cholecystitis.

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Thallium 201 Myocardial Imaging in the Diagnosis of Coronary Artery Disease

Thallium 201 stress scintigraphy has now been widely accepted as an important clinical tool that substantially improves the accuracy in diagnosing noninvasively the presence, extent and severity of coronary artery disease. The ^{201}Tl tracer is administered during peak exercise. The immediate post-stress images reflect regional myocardial blood flow, whereas the delayed images—that is, recorded four hours later—reflect myocardial viability. A transient defect (one that resolves from the early to the late images) represents stress-induced ischemia, whereas a persistent defect usually represents myocardial scars. Because the ^{201}Tl distribution in myocardium reflects the pathophysiologic consequences of coronary stenosis on myocardial blood flow rather than on the coronary anatomy, the test provides functional information that is not available through routine coronary arteriography. Compared with electrocardiography (ECG), images obtained with the use of ^{201}Tl yield accurate information on location, extent and number of myocardial segments affected by ischemia as well as the presence of necrotic or scar tissue, information that is of considerable prognostic value in patients with ischemic heart disease.

The sensitivity (80%) and specificity (91%) of ^{201}Tl stress testing for detecting coronary artery disease are considerably higher than those of electrocardiographic stress testing (60% and 81%, respectively). An important consideration for the clinical use of ^{201}Tl stress scintigraphy is that the probability of coronary artery disease developing in a given person after the test largely depends on the pretest probability as determined by age, sex, symptoms and risk factors. Thallium 201 stress testing affects the probability of disease only little in patients with a high pretest probability. Routine diagnostic use of the test therefore does not appear justified in this particular patient population. By contrast, the test considerably alters the probability of coronary artery disease in patients with a moderate pretest probability. Accordingly, the exercise ^{201}Tl scan is clinically indicated in patients who have (1) typical chest pain but no resting or stress ECG abnormalities, (2) abnormal findings on stress ECG but no symptoms, (3) atypical chest pain and equivocal results of stress ECG and (4) known ischemic heart disease considered for surgical treatment in order to gain additional prognostic information before and after operation, and to assess the physiologic significance of a questionable coronary artery lesion seen on angiography. Other indications for ^{201}Tl stress scintigraphy are exercise-induced chest pain but normal or minimal lesions of coronary arteries. In these patients, an inappropriate vasoconstriction (coronary vasospasm) elicited by exercise may be responsible for the anginal symptoms. Thallium 201 may then be a useful tool for clarifying the underlying pathogenetic mechanism of ischemia.

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Detection of Skeletal Metastasis—A Rational Approach to the Use of Nuclear Bone Imaging and Radiography

Since the advent of technetium Tc 99m phosphate bone-seeking radiopharmaceuticals, the relative efficacy of scintigraphic bone scanning and x-ray skeletal survey has been extensively investigated. There is substantial agreement about the results and the clinical implications of several published studies, and it is important for practicing physicians to be aware of these findings so that they may apply them more efficiently and economically in practice.

Nuclear bone scanning is significantly more sensitive than x-ray studies in detecting metastatic bone lesions. In considering metastatic lesions of all origins, the nuclear scan will detect about 80% more lesions than radiography, whereas only about 2% of lesions seen radiographically will not be detected on the nuclear study. Most of the cases missed by nuclear bone scanning are due to specific conditions. Given the clearly superior sensitivity of nuclear bone scanning compared with radiology in the detection of metastasis, together with the fact that this procedure is less laborious and involves less radiation to patients, it is, in most instances, the method of choice in the screening of patients for metastatic bone disease. It has been shown that areas that are positive on bone scan frequently take from 6 to 18 months to be noted radiologically.

While a nuclear study is extremely sensitive, postive findings are often not specific enough to make a diagnosis of metastatic disease with certainty. It is therefore most important that x-ray films be taken of scintigraphically positive areas to rule out benign disease. Multiple scattered areas of scintigraphic abnormalities in the absence of abnormal x-ray findings usually imply the presence of metastatic disease. However, given the presence of a primary malignant lesion, a single area of abnormality on bone scan correlates with metastatic involvement in about 50% of cases and, if that area happens to be a rib, in only 20% to 24% of cases. Thus, in patients with a single abnormality noted on scanning or in patients who have multiple abnormalities and normal findings on x-ray, "coned-down" views or computed tomography of limited areas may more clearly define the nature of the lesion(s). Bone biopsy may be indicated if results of tomography are not diagnostic and the definitive answer to that question will affect the immediate treatment plan. Otherwise, follow-up studies usually provide the information needed.

The most likely metastatic lesions to be missed on bone scans are due to multiple myeloma, thyroid carcinoma and some rapidly progressing lesions that are purely lytic on x-ray study.

In general, roentgenography is more helpful in following known metastatic lesions for response to therapy. Bone scintigraphy, on the other hand, may show increase in uptake of the radiopharmaceutical agent in a previously identified lesion because of healing or deterioration.

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BEHIND THE FACE OF HYPERTENSION

New evidence for central control

Informed Consent in Emergency Settings

JONATHAN BORAK, M.D. AND SUZANNE VEILLEUX, PH.D.

> ... The free citizen's first and greatest right, which underlies all others—the right to the inviolability of his person, in other words, his right to himself—is the subject of universal acquiescense, and this right necessarily forbids a physician or surgeon, however skillful or eminent, who has been asked to examine, diagnose, advise and prescribe (which are at least necessary first steps in treatment and care), to violate without permission the bodily integrity of his patient .... [1]

The ageless principles of personal autonomy and self-determination provide foundation to the modern doctrine of Informed Consent. In idealized form, this doctrine holds that no patient may be subjected to diagnostic or therapeutic maneuvers without first being informed of all the potential risks and benefits associated with each procedure and its alternatives and, secondly, without the patient's express consent to the proposed medical maneuver. This permits patients to maximize the opportunity to exercise autonomous behavior and offers protection from unwanted invasions of their "physical and psychic integrity."[2]

In practice, this doctrine is not always easily applied. For one, there is a paucity of operational standards by which to assure that adequate information has been conveyed to each patient and disagreement exists between the various state legislatures as to the theoretical approach to be taken in setting such standards.[3] Furthermore, patients may not actually understand the information that is disclosed to them: empirical studies have repeatedly shown that patients generally have poor retention (and, by inference, poor comprehension) of important medical data presented to them by physicians.[4-6] Although Courts have held that the requirement for informed consent is not satisfied when consent is given without full understanding,[7,8] there is evidence that, in some settings, a majority of "consenting" patients could not understand the informational basis for the treatment consented to.[9]

Even more troublesome are those aspects of the doctrine that come to bear when patients are deemed not capable of participating in the consent process. Two examples of such incapacity to participate were specifically named by Justice Cardozo in a landmark decision upholding the right of patients to self-determination: "Every human being of *adult years* and *sound mind* has a right to determine what shall be done with his own body ..."[10] (emphasis added). As currently formulated, such special circumstances or "exceptions"[2] to idealized Informed Consent include the cases of minors, of individuals deemed incompetent to make decisions whether by reason of thought disorder, intellectual impairment or altered sensorium, and of victims of emergencies when delays in treatment while consent is being obtained would lead to clinical deterioration and compromise.

These "exceptions" often pose particular consent problems for emergency physicians who are most often called upon to treat victims of unforeseen emergencies. Additionally, emergency rooms generally provide community resource for the acute evaluation and management of persons severely intoxicated, confused, suicidal or unconscious. Moreover, they are frequent providers of care to the homeless, the runaways and other unsupervised minors who are often afraid or unable to obtain medical care from more traditional sources.

What poses particular ethical difficulty in dealing with such patients is that, regardless of the rules or legal principles which might exist, the determination of whether an individual is incompetent or too critically injured to give consent must usually rest on medical judgment. Although such judgments are easily made for cardiac arrest victims, it is significantly more difficult to distinguish confusion from incompetence, urgent from emergent or to validate apparent maturity. The ap-

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plicable law rarely gives clear guidelines as to how these decisions should be made. Moreover, special protection and exceptions are granted by statute to specific patient groups in some states but not in others.

Nevertheless, there are general guidelines which serve as useful starting points in developing departmental or hospital policies covering issues of Informed Consent, a number of which are especially relevant to emergency physicians. In discussing these below, we will refer to specific Connecticut statutes to illustrate the sorts of speical considerations that states may require.

Victims of Emergencies

It is generally held that a physician need not obtain informed consent before initiating treatment to a patient who is suffering a genuine emergency. In such situations, it is argued, a 'reasonable' person would consent to treatments that "might reasonably be necessary for the preservation of his life or limb" and, therefore, consent on the part of the injured person would be implied.[11] Support for this view of 'implied' consent is found throughout as a general tenet of Tort law.[12]

Unfortunately, there are no global definitions of 'medical emergency' which might prove useful to the judicial process[13] and courts have consequently developed standards which are sometimes inconsistent. On the one hand, need for informed consent has been obviated when "the patient is unconscious or otherwise incapable of consenting, and harm from failure to treat is imminent."[14] On the other hand, some courts have extended this exception to include cases where immediate treatment would alleviate "pain and suffering" even though life and limb were not at risk.[15] It follows that, with the exception of some uncontestably life-threatening situations such as cardiac arrest, the presence of an emergency must be determined by a physician using medical judgment. However, medical judgment is reviewable by the Courts and the physician's decision may thus be overruled.

It may prove more operationally useful to invoke the emergency exception only when it is "impractical" to secure consent and when time-delays pose significant risks to the patient.[16] If a patient is either unconscious or in such pain that he is incapable of fully comprehending information presented by a physician, there is no benefit gained by involving that patient in a discussion of medical risks and only harmful time-delays can result.

Some emergency situations allow the possibility of compromise between endeavoring to obtain traditional informed consent and electing to forgo that process altogether. For example, a physician may obtain consent from a conscious patient even though complete disclosure of risks is not practicable.[2] Such a solution was found acceptable in the case of a patient suffering traumatic amputation of a finger where the patient was able to decide between simple wound closure and attempted reimplantation although time did not permit an extensive discussion of the clinical implications of the alternatives.[17]

Another compromise is to obtain 'substitute' consent for treatment from close relatives of an emergency patient who cannot participate in decision making. A physician "should, as current law requires, attempt to secure a relative's consent if possible"[14] in this setting. There is no Connecticut statute determining the order in which relatives may legally consent for emergency treatment. Such a formula does exist, however, in the state's Anatomical Donations Act[18] which lists the order of consent as: (1) spouse; (2) adult child; (3) parent; (4) adult sibling. In the absence of such relatives, consent may be sought from anyone apparently in a position to care for the patient such as an adult friend or a more distant relative.

In the event that no one is available to provide 'substitute' consent or when time does not permit efforts to locate an appropriate individual, a physician should carefully document the clinical situation which precluded such efforts. Unsuccessful attempts to contact relatives should also be noted. In the absence of consent, it is wise to obtain and document the opinion of a second physician regarding the necessity of emergency treatment so long as this second opinion does not result in time-delays harmful to the patient.

Incompetency

An individual who lacks the capacity to make decisions, in other words a person of unsound mind, is usually regarded as 'incompetent' to give effective consent for medical treatment. This point has been a touchstone of Informed Consent law since its early beginnings[1,10] yet there exists no unified standard for determining the status of incompetence. Statutory provisions and court decisions are highly variable.

Not only is a working definition of incompetency lacking but there has been little effort toward developing a theoretical framework for dealing with this issue except for the work of Meisel and his colleagues.[2, 19, 20] These authors propose to evaluate incompetence in light of certain conceptual aspects of decision-making specifically related to informed consent decisions. This specific model assumes that a patient is actually competent to consent unless specific evidence can be found to the contrary. The onus is therefore explicitly upon a physician to recognize and document those findings which indicate incompetence.

The authors propose four approaches for evaluating competence with this model. For one, a patient might be judged incompetent if he or she makes no decision when a decision is necessary and demanded. Termed the "presence of decision" test, this criterion presumes an individual competent so long as some decision is made, regardless of its quality of logic, and represents an extreme view favoring personal autonomy.

Secondly, competence could be assessed by evaluating the criteria used by the patient in reaching a decision. For instance, once a patient had made a consent decision, inquiry should concentrate upon the patient's decisional methods. A patient who indicated that there was no reasonable basis for deciding or whose decision was based upon apparently irrelevant issues might be found incompetent to decide. This approach imposes paternalistic values and abridges patients' self-determination.

A third approach consists in examining the nature of the patient's decision. A patient who chose no treatment over necessary treatment or a high-risk procedure over a comparable low-risk one might be deemed incompetent. However, such a standard would directly threaten the ethical foundation of Informed Consent because it would deliberately subjugate patient autonomy to medical values.

Implicit in the concept of "informed consent" is the idea that the information presented during disclosure is adequately understood. Thus, as a fourth alternative, a patient able to comprehend such information could be found competent irrespective of the actual decision made. The problem here relates to the lack of readily available standards for judging comprehension; physicians' expectations of their patients 'intelligence' would greatly vary and the differing ability of physicians to communicate technical material would also render such findings highly subjective.

An altogether different approach proposed by Meisel et al is tied to the concept of "general" incompetence. The standards previously described would evaluate incompetence specifically in the context of Informed Consent decision-making. Tests of general incompetency would consider an individual's ability to function in the world, as a *person,* rather than simply in a medical context, as a *patient.* Examples of general incompetence are acute intoxication, mental retardation and psychosis.

The theory of general incompetence is especially attractive because it lends itself to nonsubjective testing such as blood alcohol determinations. However, mechanistic criteria tend to ignore the fact that the specific capacity to make Informed Consent decision may be retained by a patient who is otherwise generally incompetent. This is recognized in numerous states where psychiatric patients, whether competent or otherwise, are granted unqualified right to refuse either electroshock therapy or psychosurgery.[21] Hence, it is often preferable to determine that a patient is specifically incompetent to participate in Consent decisions once general incompetence has been found.

Connecticut statutes do not provide specific guidelines for the determination of incompetency, leaving such judgments to physicians except in those cases where incompetent adults have a Court appointed Conservator of the person. Unless an emergency situation exists, an incompetent patient may not be subjected to treatment without prior substituted consent. If incompetency is likely to be only temporary, as with alcohol intoxication, it may prove best to delay nonurgent treatment until the patient is capable of consenting. If a conservator of the person has been appointed, he or she is the individual authorized to consent for the patient's treatment. However, some conservators are granted only limited authority, and the right to consent may be retained by the patient, as is the case with mildly retarded adults. Such limitations are stated on the Court's certification of appointment which the conservator should have available. In such a situation, caution should be exercised in relying on the incompetent adult's consent, particularly where treatment is risky.

The absence of a conservator is no guarantee of general competency. When incompetence is suspected, in addition to the patient's consent, it is advisable to obtain consent from a close relative or friend, following the order described in the Anatomical Donation Act.[18] In non-routine situations, as when risks associated with treatment are especially great, it may be necessary to ask the family to seek appointment of a conservator.

In dealing with incompetent patients, a physician is well advised to make careful documentation of the reasons for finding incompetence including laboratory results and clinical obervations. In uncertain cases, it is often preferable to obtain a second opinion before electing to deny a patient's right to consent. A psychiatric consultation may be particularly useful.

Minors

In order for Informed Consent to be legitimate and meaningful, it is necessary that the consenting individual be of sufficient maturity to understand the nature of the underlying medical problem and its associated risks. Here, as in other legal matters, maturity is usually determined on the basis of a person's age. In Connecticut and most other states, legal maturity or adulthood begins at the age of eighteen years. Individuals below that age are classified as 'minors' and are given limited discretionary rights. They are, in other words, legally incompetent.

As a general rule, a minor may not consent to medical treatment and a physician should obtain consent instead from a parent, a court-appointed conservator or some other adult acting *in loco parentis.* But in the setting of a genuine emergency, as discussed earlier, it may not be practicable to obtain parental consent and proper treatment should not be withheld. Some courts have held that the parents of a minor who has received such emergency care may not recover damages from the physician who administered the treatment simply because their prior consent was not obtained. Moreover, they remain financially liable for the emergency medical expenses so long as they otherwise contribute to the minor's support.[22]

In the absence of a true emergency, parents might have a cause of action against a physician who gives treatment to their minor children without their consent even when that treatment has been properly performed and was medically indicated.[23] The parents also have the right to refuse financial responsibility for such medical care.

The need for parental consent is often greatly restricted by judicial and statutory exceptions. In these exceptional situations, minors are treated as having adequate maturity to make consent decisions. The law also recognizes that for certain types of medical problems, obtaining parental consent could prove so problematical that the minor might avoid necessary treatment rather than confront parental disapproval and ire.

One such important exception relates to the common law concept of 'emancipation.' An emancipated minor is one who has assumed the responsibilities of adulthood, usually by willingly living apart from his/her parents and managing his/her own financial affairs. In addition, a minor who is legally married or who is serving in the Armed Forces is held as a matter of law to be emancipated. In Connecticut, such a minor may obtain a court order of emancipation but this judicial procedure is not usually necessary since emancipation can be more simply established according to traditional common law standards. An emancipated minor may participate fully in Informed Consent decisions regarding his/her own medical care. Furthermore, Connecticut law states that any minor who has borne or fathered a child may give effective consent for the treatment of his or her child.[24]

A minor may also be given treatment without parental consent under the doctrine of the 'mature minor.' This doctrine holds that when parental consent cannot be obtained and treatment is necessary, a physician may act upon the signature of the minor so long as the minor is at least fifteen years old, appears capable of fully understanding the medical situation, has received full disclosure of risks and grants consent to treatment. Such consent is only valid for medical acts intended for the minor's own benefit; it is not valid for purposes of research or organ donation.

It is wise for a physician invoking the 'mature minor' doctrine to carefully document the efforts made to contact family members as well as the need for treatment. In cases of doubt, it would also be advisable to obtain the opinion of a second physician who would document that treatment is necessary. We know of no situation where a physician or hospital has been held liable for relying on the consent of a mature minor when such consent was properly obtained.

Of a different nature are exceptions to parental consent pertaining to minors seeking treatment for veneral disease or substance abuse. In these situations, treatment may usually be provided based solely upon the minor's consent. Some authorities have argued that these exceptions are justified on the ground that the underlying disorders pose an "obvious .... medical emergency."[22] A more likely explanation for the statutory protections granted to minors in these cases reflects the dual concerns that societal health objectives are better served by treating such conditions and that requiring parental consent might discourage some minors from seeking appropriate medical care.

That this latter explanation is the more probable is supported by the fact that parental notification of treatment is often prohibited. Connecticut law permits treatment of minors with venereal disease without parental consent. It further requires that this treatment be kept confidential and that a bill for these services may not be sent to any person other than the minor patient.[25] However, if the minor is twelve years old or less, the matter must be reported as possible child abuse. A separate statute also allows a minor to obtain treatment for drug abuse, including voluntary treatment in a licensed facility, without parental consent and prohibits parental notification.[26] In treating these minors, it is probably better for a physician to encourage the patients to inform their parents but such actions are not required by law.

Minors suffering from mental illness present still more complicated issues of consent. In Connecticut, sixteen and seventeen year old minors have the right to submit themselves to voluntary psychiatric treatment, including the power to sign themselves into hospitals as voluntary mental patients. In so doing, these minors are guaranteed all the rights enjoyed by adult patients including the right to refuse specific treatment or medications. Younger minors, those aged fourteen or fifteen years, may also voluntarily undergo psychiatric treatment without parental consent. However, for these individuals, parental refusal for treatment is held to supercede the child's consent. Therefore these younger minors may consent to such treatment only if their parents do not specifically object.[27]

Summary

The legal doctrine of Informed Consent poses particular challenges to Emergency physicians that are not generally confronted by most clinicians. Because of the nature of episodic Emergency care, these physicians often have limited access to such information as patients' specific cognitive impairments and the availability of guardians or conservators. Furthermore, many emergency patients present problems requiring prompt medical response which preclude prolonged consent deliberations. The onus rests therefore heavily upon Emergency physicians to substantiate and justify treatment decisions when consent is not obtained.

In order to deal with these complex consent issues, we urge that Emergency physicians consider several general guidelines as starting points in developing appropriate departmental policies. For one, specific documentation should be made whenever patients, for whatever reasons, are denied participation in consent decisions. Whenever practicable, second opinions should be documented which substantiate either patient incompetence or the presence of medical emergency.

Second, efforts to obtain substitute consent should be made in all cases except where specifically prohibited by law and these efforts, whether successful or not, should be documented. Finally, a careful review of statutory requirements should be made on a state-by-state basis so that peculiar rules or exceptions can be understood and followed.

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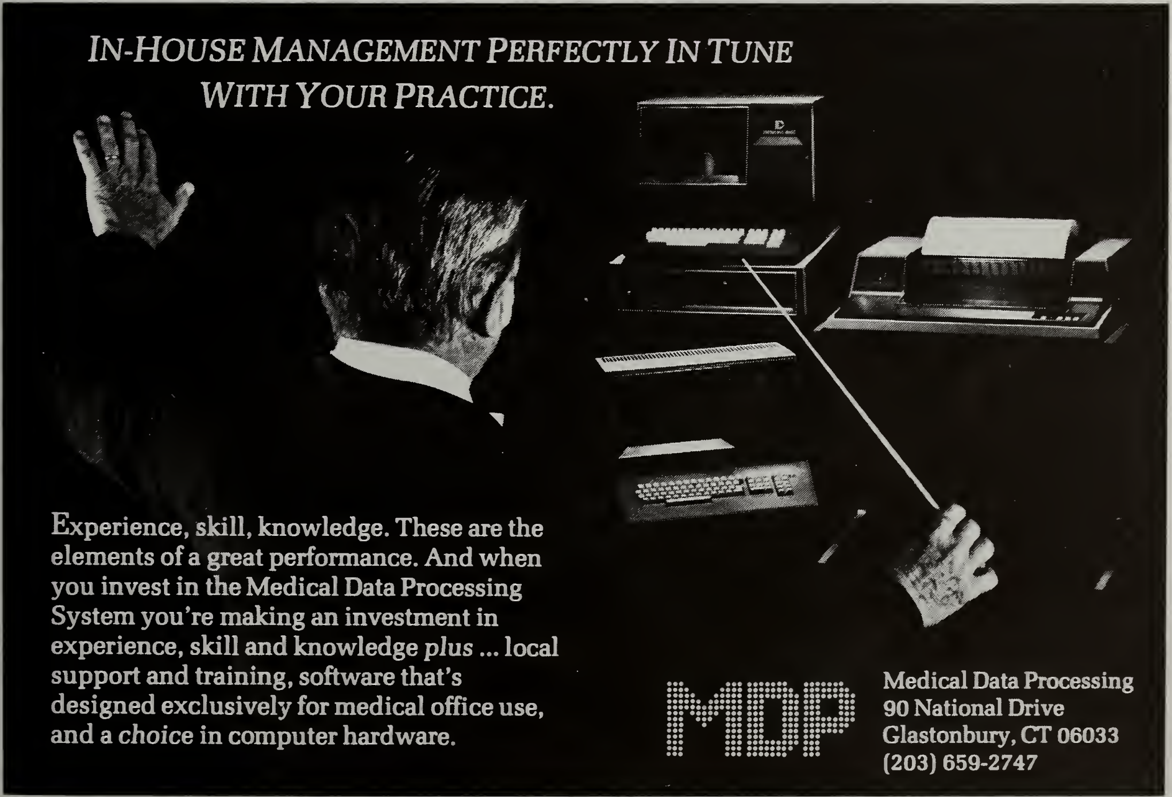

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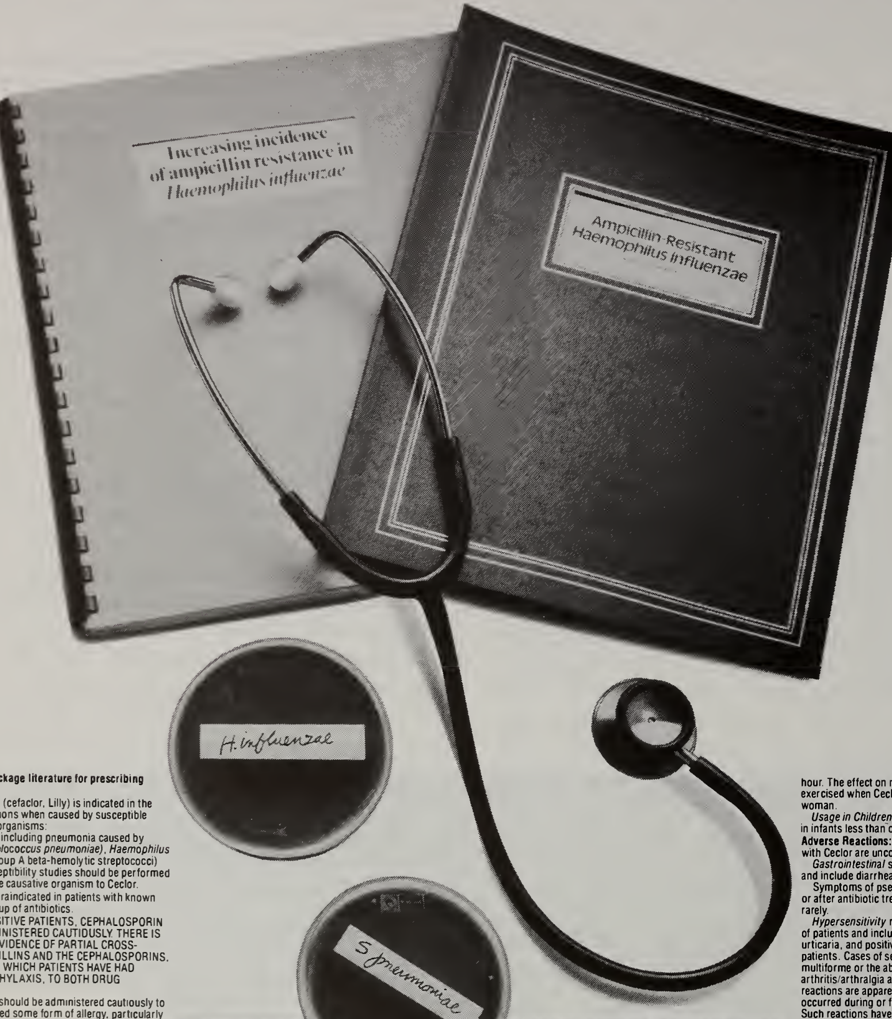
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Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor.

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: *General Precautions*—If an allergic reaction to Ceclor occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy—Pregnancy Category B—Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers—Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor® (cefaclor, Lilly) is administered to a nursing woman.

Usage in Children—Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below:

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain—Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic—Slight elevations of SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic—Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal—Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

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*Many authorities attribute acute infectious exacerbation of chronic bronchitis to either *S. pneumoniae* or *H. influenzae*.[8]

Note: Ceclor is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Peaceful Coexistence in Connecticut

DAVID D. AGAHIGIAN

Introduction

During the 1983 legislative session the State Senate considered a bill that would have amended the Connecticut Optometry law. The existing law precludes optometrists from utilizing drugs or surgery in the care of patients.[1] The proposed bill sought to allow the use of certain drugs by optometrists. This initiative was vigorously supported by the Connecticut State Optometric Association and equally opposed by the Connecticut Society of Eye Physicians.

The bill was granted a hearing before the Public Health Committee of the Senate. The Optometric Association and the Eye Physicians each presented five speakers before the committee. The bill was voted out of committee and sent to the floor of the Senate for a roll call vote. It was soundly defeated 24-12.

After the vote several of the legislators expressed a growing impatience with Connecticut's optometrists and ophthalmologists. Since 1977 this bill, with minor variations has been proposed by the Connecticut State Optometric Association five different times. Concurrently, Connecticut's ophthalmologists have proposed a handful of legislative initiatives seeking to limit the professional activities of optometrists.[2] The two professions have used the Connecticut legislature as a battleground and are rapidly alienating the lawmakers.

The political activity has been costly. The two groups spent over $23,000 in lobbying fees in 1982.[3] What could prove to be more costly is the legislators' disdain for this political activity. A sufficiently irritated legislature could unilaterally impose their own settlement of the optometry-ophthalmology impasse with disastrous consequences for both professions.

Traditionally ophthalmologists have practiced in urban areas close to major hospitals, while optometry has been a rural profession with a wider distribution of manpower. This is not relevant in a densely populated state such as Connecticut where every citizen is physically close to an optometrist or an ophthalmologist. Ophthalmologists are well represented in Connecticut where there are approximately 200 active ophthalmologists and 300 active optometrists. The national ratio is about 150 ophthalmologists for every 300 optometrists.[4]

A priority for each of the 500 eyecare professionals in Connecticut should be to move their debate outside the state legislative process. Optometry is not getting any closer to passing the drug bill, and ophthalmology has no legislative goals outside of defending the status quo. Optometry and ophthalmology need to work together to resolve their differences.

Each profession should select a handful of members to serve on a bipartisan committee.[5] It is essential that the representatives be diplomatic, as well as dedicated to the goals of such a committee. To build a solid foundation of bipartisan feeling the committee should address issues that are vital, yet peripheral to their differences. The committee could:

1. Evaluate the services for the blind in Connecticut. If they are found deficient, propose legislation to improve these services.
2. Review the school vision testing procedure and determine if they need change or standardization.
3. Evaluate whether the motor vehicle vision requirements are outdated. With the advances in eyecare people may be needlessly restricted from vehicle use.
4. Promote eye safety in the workplace and in school athletic programs. The committee could meet with business leaders and school officials to effect meaningful change in eye safety.

From this point the committee could move to the more delicate and controversial subjects, for instance, the drug bill. Resolving these issues will be difficult, and may be impossible. However, these issues should be decided by professionals who really understand the problem. Most legislators are ill equipped to deal with technical topics concerning health care. This committee

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would have other advantages. This is less expensive and more productive than the annual marches to the Capitol Building. If the committee achieved only a new standard of eye safety in the workplace it would be a success. What is often forgotten is that outside the political arena the goals of optometry and ophthalmology are practically identical. It is hoped that the two professions can unite to advance toward these admirable goals.

Most medical people view the agitation between optometry and ophthalmology as an economically inspired fracas unique to eyecare. This a simplistic interpretation of a complex situation. Increasingly physicians are competing with non-medical health care practitioners. The competition problems that have plagued ophthalmology will present themselves to other specialties in medicine.

In this article four main points of contention between optometry and ophthalmology are presented:

1. Differences in treatment of the same problem
2. Limitation of the nonmedical practitioners duties
3. Insurance company and government reimbursement rules
4. The professions' roles in a national eyecare system

It is hoped that physicians outside ophthalmology can gain from this article an awareness of the recurring differences between medical and nonmedical health care practitioners.

I. Differences in Treatment

Many nonmedical health care practitioners distinguish their professions from medicine by their approach to common problems. Optometry has diverged from medicine in the treatment of strabismus and learning disabilities.

The optometric model for treatment of strabismus is based upon a plastic neural-ocular axis that can be altered by a battery of eye exercises. They contend that this can result in eye alignment. The data supporting this model are sparse and often anecdotal. The experiments on this subject are virtually impossible to control. Thus, it is unlikely that any study concerning eye exercise efficacy will strictly adhere to the scientific method.

Ophthalmology takes a predominantly surgical approach to the correction of strabismus. It consistently criticizes the optometric model as scientifically unproven, and therefore invalid.

Optometry also believes that decreased visual skills are a large component of learning disabilities and reading deficiencies. They maintain that eye exercises which improve certain visual functions can have a favorable impact on reading and learning deficiencies. Ophthalmology again points to the lack of scientific evidence supporting this viewpoint. Because the etiology and treatment of these problems are still uncertain this debate will remain alive for many years.

II. Limitation of Nonmedical Practitioners

Optometry is a relatively new profession. Its roots are traced to the late 1800s when ophthalmologists, more concerned with eye disease, were doing an inadequate job of measuring and correcting refractive error. The dispensers of eyeglasses, the opticians, reacted to this unmet need by advertising themselves as refracting opticians. Soon the refracting opticians sought recognition as an independent profession (optometry) through state legislation. Ophthalmologists fought the "professionalization" of optometry claiming that optometrists were practicing medicine without proper education. Optometrists countered this argument by using the slogan "a lens is not a pill" in reference to the non-invasive methods of optometry. By 1925 every state had an optometry law. Most, if not all, specifically prohibited the use of drugs or surgery by an optometrist.

By law, the optometrist was also a detector of disease. This was a difficult task without the use of pupil-dilating drugs. By the late 1960s optometry schools were teaching ocular pharmacology and there were legislative proposals in many states seeking to grant optometrists the limited use of ocular drugs. In 1971 Rhode Island became the first state to pass an optometry drug bill. Presently over 30 states directly or indirectly have given optometrists the right to use diagnostic eye medications. Two states, North Carolina and West Virginia, allow optometric utilization of therapeutic drugs.

When arguing against the drug bills ophthalmologists have raised the following objections:

1. The drug bill causes further overlapping of services provided by both professions, resulting in a less effective marketplace.
2. Optometrists have insufficient education to utilize the drugs and deal with possible side effects.
3. Optometrists have inadequate experience with eye diseases to definitively determine if, indeed, an eye is diseased.

III. Reimbursement Rules

A substantial portion of the eyecare dollar is dispensed by insurance companies and state and federal government. Therefore optometrists and ophthalmologists have a vested interest in the reimbursement rules. This has produced numerous legislative battles between the professions addressing questions such as:

- Who should be reimbursed for Medicare/Medicaid patients?
- Should all insurance plans offer a choice between optometrists and ophthalmologists?
- Who should administer eye examinations to school children?
- Who should perform eye examinations on the prison population?
- Should optometrists be considered expert court witnesses?

While these questions are monetary in nature, the answers mean much more than a change in someone's income. Each time that optometry wins one of these legislative battles, it is further legitimized as a profession. These optometry victories also blur the distinction between the professions in the eyes of the public.

IV. Roles in a National Eyecare System

Each month brings a new national inflation report which invariably shows health care costs rising far in excess of general inflation. As the nation's health care costs skyrocket the government will become more aggressive in its attempt to control costs. National Health Care, seemingly a dead issue, could be revived. This is where government may choose to formulate a final solution to the optometry-ophthalmology debate.

Optometry envisions an eyecare delivery system that designates the optometrist as the only entry point. If the optometrist detects disease or the need for surgery, then the patient would be referred to the ophthalmologist. To promote this idea optometrists call themselves primary health care providers, and refer to ophthalmologists as secondary providers. This has been a successful strategy. Optometrists are now the eyecare entry point in many of the Armed Services and Veterans Administration Hospitals.

This is disturbing to most ophthalmologists. A vast majority of ophthalmologists spend considerable time determining refractive error and diagnosing eye disease. If these duties become the sole province of optometry, there would be thousands of underemployed ophthalmologists. There simply is not enough eye disease to occupy the approximately 11,000 ophthalmologists in the United States.

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New Lease on Medicare's Life?

The predicted bankruptcy by 1990 in the Medicare hospital trust fund may be held at bay for a few years past that time if some recent improvements in the status of the fund hold up.

The new projections from the Congressional Budget Office (CBO) were issued along with another CBO report on the federal deficit, however, which projects that Medicare and Medicaid will consume 3% of the gross national product by 1990 and suggests options for holding down Medicare spending. In addition to a Medicare fee freeze or fee schedules, the alternatives include freezing surgical fees or restricting fees for physician services in the hospital to the fee that would have been charged if the service had been done on an outpatient basis.

As recently as last November, CBO had estimated that the Medicare hospital fund would be down to $8 billion in 1989. Now, CBO says that the fund is likely to show a balance of $30 billion in 1989. Bankruptcy is not projected until an unspecified date in the "early 1990s."

* * * *

PRO Regulations, Finally

Final regulations needed to open the bidding process for Medicare's new review system were published by the government in late February.

Medicare officials say that will give them plenty of time to get the new peer review organizations (PROs) up and running before the October 1 deadline imposed by law. But the architect of the law and physicians who will be called upon to work under it contend that Administration footdragging has jeopardized physician participation in the reviews and threatened the credibility of Medicare's prospective pricing system.

The White House Office of Management and Budget had objected to the regulation as written by HHS, not because of the substance but because of differences over the "scope of work." The regulations had been scheduled for publication in mid-February, but the squabble held up their release.

* * * *

Physicians and Seniors Groups Building New Ties

Despite some very real differences of opinion, physicians and the nation's elderly appear lately to be moving toward serious reconciliatory efforts.

A warming of relations between organizations representing the two groups was obvious in recent Senate hearings and at a meeting of the country's largest organization of senior citizens—the American Association of Retired Persons.

The new attitude seems based in part on a belief by groups that it will be up to physicians to assure that their elderly patients continue to receive all the care they need under Medicare's diagnosis related groups (DRGs) pricing system.

One signal of possible new cooperation between the two groups came during a Senate Finance Subcommittee investigation into the Reagan Administration's implementation of the peer review organizations that are to scrutinize care under the DRGs. Physician members of the American Medical Peer Review Association and the American Medical Association along with AARP representatives all criticized the Administration for dragging its feet in issuing the regulations and bids needed to get the PROs underway. All three groups said they want physicians—not insurance companies—to do the review. AARP President-Elect Vita Ostrander complimented the AMA on its interest in the issue.

Repeating similar sentiments a day later at AARP's Legislative Council, Ostrander asked AMA Executive

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Prepared by the Washington, D.C.
Office of the American Medical Association

Vice President James Sammons, MD, whether the AMA "will assist PROs in collecting data on dumping" of patients under DTTGs and whether the Association will "extend this commitment to state associations."

The answer, responded Dr. Sammons, is "an unequivocal yes." The AMA "believes strongly" in the PRO effort and has "insisted that the state medical society should be the agency that applies for designation as the PRO" in order to assure that the review process becomes a "quality of care measure" rather than strictly a cost issue. "Clearly there has to be a cost factor," he said, but "we don't want to lose sight of quality.

* * * *

Warm Hill Reception for Heckler

HHS Secretary Margaret Heckler got a generally friendly reception in Senate Finance Committee hearings on the President's 1985 budget proposal.

Only Republicans attended the hearing at which Heckler noted that her Department will spend more than $36 million an hour and, in a departure from previous years, several members said they thought changes proposed for Medicare may not be extensive enough.

Most of the budget's health proposals are recycled from last year, with the most significant change in the Medicare and Medicaid area being the absence this year of a proposal to increase Medicare Part A cost-sharing for short hospital stays while eliminating it for illnesses lasting longer than 60 days. The budget again includes a freeze on physician's Medicare fees.

Heckler said the copayment restructuring was dropped because she believes it unwise in view of the prospective payment plan's incentives for lower hospital utilization. Sen. Steve Symms (R-ID) expressed disappointment that the Administration chose to remove the copayment changes and Sen. John Chaffee (R-RI) suggested that the budget proposals don't go far enough toward solving Medicare's financial problems.

"I'm afraid we may undermine public confidence" in our seriousness about dealing with the Medicare program if we just enact these changes, Chaffee said. "It is nice to say, 'oh, you can get it from the doctors or you can get it from prospective payment', but the truth is that beneficiaries are going to have to share."

* * * *

Finance Budget Deficit Plan

At the behest of Chairman Robert Dole (R-KS), the Senate Finance Committee has begun consideration of a four-year, $100 billion deficit reduction plan that includes a three month freeze on fees for all and a two-year freeze on Medicare increases for physicians who choose not to accept 100% of Medicare claims on assignment.

On February 27, AMA Executive Vice President James H. Sammons, MD, wrote to Sen. Dole outlining AMA's call for a voluntary fee freeze of one year and asking the Committee to reconsider its "participating" physician proposal until physicians could show that a voluntary effort would work.

The eventual enactment of the plan of any of the Senate Finance provisions is far from certain, since the committee has stipulated that its deficit-trimming offering is contingent on similar action in other areas, including the defense budget.

About $1.6 billion of the approximately $5.5 billion worth of Medicare cuts would come from the physician fee freeze. Similar to one advanced in the committee before the Congress recessed last fall, the proposal would affect all physicians for three months. As of April 1, 1984 Medicare's prevailing fees would be rolled back to the June 30, 1983, level and frozen until July 1, 1984.

After that time, the freeze would be discontinued for physicians who signed an annual agreement to assign claims and accept Medicare's allowable fee as payment in full for all services to Medicare patients. Although physicians who refused to sign the agreements could continue to take assignment on a claim by claim basis, their Medicare fees would remain frozen for up to two years, one year at a time.

Another major spending cut proposed for consideration would have eliminated a so-called 1% "intensity factor" used in calculating permissible increases in Medicare payments to hospitals. A target rate system in effect since 1982 limited annual increases in hospital payments to 1% plus the percentage increase in the cost of the "marketbasket" of goods and services purchased by hospitals. The "marketbasket plus 1%" limit was to continue under the new diagnosis related groups system until 1986, after which time the HHS Secretary is to determine increases in DRG payments.

Sen. David Durenberger (R-MN) refused to endorse the committee proposal which would have limited increases in 1985 and 1986 to the marketbasket increase. Instead Durenberger offered a modification which eliminates the 1% intensity factor only in the portion of a hospital's costs reimbursed under the old (pre-DRG) system, for a savings of $1.1 billion instead of $2.3 billion over four years.

Other provisions agreed to by the committee include:

- an increase in the Medicare Part B premium each year beginning in 1985 until by 1990 it would equal 35% of the total Part B benefit costs. Premiums would be $43 per couple per month higher in 1990 than they would have been under current law.
- a delay in the eligibility for Medicare entitlement until the first day of the month following the individual's 65th birthday.

- a provision making Medicare the secondary payer in instances where a Medicare beneficiary is also covered by a working spouse's employer plan.
- establishment of a fee schedule for clinical lab services. The fee would be set at 62% of the prevailing charge levels and would apply to hospital outpatient labs as well as independent, although Sen. John Heinz (R-PA) was at press time considering an amendment to further reduce that rate to 60%.
- extension of the current 3% reduction in federal Medicaid payments to states for another three years.

* * * *

'Baby Doe' Legislation Passes House; Setback Seen to Physician Groups

Opponents of "Baby Doe" legislation suffered a major setback in Congress in February, when the House of Representatives passed legislation to establish treatment requirements for handicapped newborns.

The bill, approved by a large 52-vote margin, redefines child abuse to include withdrawal of nutrition of medically-indicated treatment. States must set up procedures to ensure that newborns get proper care and attention in cases of suspected neglect.

States that choose not to comply risk the loss of all child abuse funding. Parents or physicians who do not follow state regulations could be charged with child abuse.

Debate on the bill, described by one House member as "the most personal, gut-wrenching issue we'll face this year," was repeatedly delayed by election-conscious legislators. Once on the floor, however, it won the broad support of all but 30 Republicans, including such key figures as Jack Kemp (R-NY), Henry Hyde (R-IL), and Robert Michel (R-IL).

A last minute attempt to delete Baby Doe provisions from the bill by Rep. Rod D. Chandler (R-WA) and others failed to win support in the House. Because this substitute amendment offered federal assistance and information rather than regulations, it earned the broad-based endorsement of the medical community.

The infant care debate then expanded into an open forum on abortion, euthanasia and other "right-to-life" issues. "The law now says that the pre-born fetus is not human. Should we go the next step and say that the newborn is also not quite human? How about at the other end of life? Can we also make life-or-death decisions for people because, having become senile, they are not quite human, either?", challenged Rep. Hyde.

Countered Chandler: "My philosophy is not that we believe there is anything less human about handicapped infants. Instead we face a situation where we must decide whether there should be unlimited treatment in an attempt to sustain life."

The American Medical Association, the American College of Obstetricians and Gynecologists, and other members of the medical community fear that this legislation will encourage the government to second-guess parental and physician decisions. It may also increase the stress and trauma when an infant is born with life-threatening congenital impairments, without the promise of real benefit in treatment, they say.

Meanwhile in New York, the U.S. Court of Appeals has ruled that the federal law which prohibits discrimination of the handicapped does not apply to treatment decisions of handicapped newborns. Neither the language nor the intent of the law—Section 504 of the federal Rehabilitation Act of 1973—gives the Department of Health and Human Services (HHS) the authority to conduct an investigation based on medical records of Baby Jane Doe, the three-judge panel concluded.

"Congress never contemplated that the Rehabilitation Act would apply to treatment decisions involving defective newborn infants. Until Congress has spoken, it would be an unwarranted exercise of judicial power to approve the type of investigation that has precipitated this lawsuit," the 48-page opinion said.

* * * *

HHS Budget Hit Hard

The fiscal 1985 budget that President Reagan presented to Congress in February would boost the Health and Human Services (HHS) authority to $324.8 billion, an after-inflation increase of 5.5%. Under this budget, HHS will spend $36.3 million an hour in benefits for more than 60 million Americans.

However, the once-skyrocketing rate of HHS growth has declined significantly, falling from an increase of 17.7% in 1981 to 7.5% in 1985. "We are striving to do more with less," explained HHS Secretary Margaret M. Heckler in a press conference.

Major entitlement programs for the elderly, disabled and poor would increase slightly; discretionary programs in disease and drug research would lose support.

In the large entitlement programs, reforms such as DRGs are credited with the slow spending. In the smaller discretionary programs, no new projects will be undertaken for the remainder of the decade, unless programs of equal cost are eliminated.

"It is vital that we spend wisely,"said Secretary Heckler. "We have a role to play in the battle against a higher deficit, increased taxes, and the threat of renewed inflation, which would erode the very benefits we provide to people.

* * * *

Organ Transplant Bill Opposed by AMA

Congress has unveiled one solution to the organ transplant problem: HR. 4080, the National Organ Transplant Act. It is eyed nervously by members of the medical community, however, who fear it will boost government costs and authority over all medical procedures.

The bill, introduced by Rep. Albert Gore (D-TN), would provide grants for organ procurement organizations and a 24-hour telephone "transplant hotline." It would also provide a data registry of patients who have received transplants.

Furthermore, it would instruct the Department of Health and Human Services (HHS) to set criteria for: patient selection, qualifications of transplant personnel, and the facilities where transplants are performed. Unauthorized facilities would receive no Medicare or Medicaid reimbursement.

The bill is strongly opposed by the AMA, which says it would provide new and unprecedented authority to HHS. HHS officials, oppose the bill as well.

* * * *

Senators Turn on DRGs

Flanked by subordinates with boxfuls of briefing materials, HHS Secretary Margaret Heckler set out in a recent appearance before the Senate Budget Committee to defend the President's 1985 budget proposals. Instead, she found herself justifying her department's implementation of Medicare's new diagnosis related groups (DRGs) payment plan.

The Senators' questions reflect criticisms hospitals have been leveling at the new program since its details were first unveiled last fall. They involve the lack of any special adjustment for hospitals treating large numbers of indigent patients, perceived inadequacies in the wage index used to adjust DRG payments for each hospital, and alleged inequities in the assignment of hospitals to either an urban or rural category.

Other areas of concern include the department's apparent reluctance to approve waivers from the federal DRG plan for certain state rate programs and the need for physician cooperation if the program is to work.

* * * *

Pathologists vs. HHS

The duties of pathologists were dissected in a Washington, D.C. federal courtroom in February. At issue in the case of *The College of American Pathologists vs U.S. Department of Health and Human Services* is whether pathologists' services should be lumped together with other hospital services or considered separately as "physician's services."

The dispute revolves around reimbursement levels. If pathology services are considered part of a hospital's general services, they are covered by Part A of Medicare; under the new prospective payment system, a hospital will only pay what it chooses to pay. But if a pathologist's job is considered to be a physician's service, he or she may charge for services like any other physician.

The government argues that pathologists' clinical lab services are not usually furnished for an individual patient, do not contribute directly to diagnosis or treatment, and do not necessarily have to be performed by a physician. The pathologist is a 'physician's physician' and thus should not charge patients directly, HHS says.

The pathologists, on the other hand, contend that members of their profession perform a personal service every time they themselves analyze or interpret test results. Technologists may perform routine work, but the pathologist's opinion is important in cases of unexpected or abnormal test results. The pathologist's decision is an important part of a patient's diagnosis, said CAP attorney Jack Bierig.

* * * *

Package Insert on 'Pill' to Change

The patient package insert of oral contraceptives received a facelift in February, reflecting the growing body of information about the dangers and benefits of the pill.

Physicians and the public are unlikely to see these revisions anytime soon, however. Earlier changes, proposed more than two years ago, still languish within the Food and Drug Administration's (FDA) regulatory pipeline. Newer changes proposed at last week's meeting of the FDA Fertility and Maternal Health Drugs Advisory Committee face similar delays.

The new label will omit warnings about breast cancer, included in previous versions. After a review of recent studies, committee members decided that there is insufficient evidence linking the pill with the disease.

It strengthens language about cervical cancer, however. For the first time, it recommends that pill users receive close clinical surveillance, including annual Pap smears.

Other warnings also receive new emphasis. Three high risk factors—heavy cigarette smoking, over 35 years of age, and conditions such as high blood pressure, obesity, diabetes, and high cholesterol levels—are preminently placed in the insert's opening section. Women are instructed that "as a general principle, no drug should be taken during pregnancy unless it is clearly indicated" and "if possible, do not use oral contraceptives while breast feeding."

And for the first time, women are provided with a list of special medical conditions—such as migraine, depression, breast nodules, and gall bladder, heart or kidney disease—that should be brought to the attention of their physicians.

One section, the first of its type to appear in inserts, describe the benefits of using the pill: lighter menstrual cycles, decreased menstrual pain and tension, reduced risk of fibrocystic breast disease, ovarian cysts, pelvic inflammatory disease, ectopic pregnancy, ovarian cancer, endometrial cancer, and rheumatoid arthritis.

Some new deletions are also conspicious: the new insert will not caution DES daughters against estrogen use; there is no mention of temporary infertility, increased risk of miscarriage, or "post-pill" symptoms experienced after stopping use; a comparison with alternative forms of birth control is omitted; and women with family histories of diabetes, stroke, and heart attack are no longer advised of possible risk. Several other conditions possibly linked to pill use—myocardial infarction, hemoblobinpathies, and melanoma—have been left off the insert until more information is available.

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Cancer Death Rates Declining

The nation's overall death rate for cancer declined between 1950 and 1979, despite a sharp increase in lung and other smoking-related cancers, according to data published in February by the Environmental Protection Agency (EPA) and the National Cancer Institute (NCI).

Excluding lung cancer, death rates for all cancers decreased 5% in white males, 12% in white females, and 13% in nonwhite females. The rates for nonwhite males increased 15%.

In contrast, lung cancer death rates increased 116% in white males, 199% in white females, 185% in nonwhite males and 188% in nonwhite females. There were also increases in deaths from eophageal and laryngeal cancers.

The new data appear in *U.S. Cancer Mortality Rates and Trends: 1950-1979,* a collaborative effort between EPA and NCI. Death rates were based on death certificates received by the U.S. Department of Health and Human Services, National Center for Health Statistics. Rates were computed for 3,065 counties in 49 states.

"The tabulations help identify counties with unusual cancer mortality patterns, which may in turn provide etiologic clues. Similaries between the patterns of cancer and distribution of risk factors are helpful in designating high-risk communities," said Thomas Mason, MD, of NCI's Environmental Epidemiology Branch and a coauthor of the reference text.

* * * *

FDA Petition to Halt Use of Two Anti-Inflammatory Drugs

The Food and Drug Administration was petitioned in February to suspend immediately use of the drugs Butazolidin (phenylbutazone) and Tandearil (oxyphenbutazone), due to alleged adverse reactions associated with their use. The petitioner is Health Research Group, a Ralph Nader organization.

Manufacturer Geigy Pharmaceuticals defends its products, saying that their risks are exaggerated and that sudden withdrawal from the market would be "devastating" to physicians and patients.

This unusual request for sudden suspension—granted by FDA once before, in 1977—is justified due to the seriousness of drug reaction, according to Health Research Group. The usual administrative procedure for withdrawing a product takes between six months and several years.

In a February public hearing in Washington, DC, HRG urged that only controlled distribution of the powerful nonsteroidal anti-inflammatory drugs (NSAIDS) should be permitted. The small number of patients who need the drug could get it by asking their physicians to file an Investigational New Drug Application, according to HRG.

The drugs have caused a total of 3,100 deaths in the United States contends HRG medical director Sidney Wolfe, MD. Safer and equally affective alternatives exist for virtually all conditions now treated with the drug, he says.

The risks do not exceed those of other NSAIDS, counter manufacturers. The total number of adverse reactions "are neither unexpected nor disproportionate," says Marvin Wetter, MD, Geigy spokesman. The incidence of deaths resulting from use of Butazolidin and Tandearil is .0006%, lower than that of other NSAIDS Nalfron, Clinoril, and Naprosyn. All nine of the commonly prescribed NSAIDS cause the same reactions as Butazolidin and Tandearil, he contends.

Furthermore, most physicians are familiar with the risks, Wetter adds. "The American medical community is well aware of the drugs' adverse effects—this is no new information," he said.

* * * *

Fetal Pain Controversy Bared

A coalition of physicians have rallied behind President Reagan, supporting his contention that aborted fetuses suffer "long and agonizing pain."

"A fetus shows the precise behavior as you or I in avoiding pain. It is not a reflex, but an actual aversion to a needle or chemicals. He squirms away from any noxious influence," said spokesman Vincent Collins, MD, professor of anesthesiology at Northwestern University in Chicago, in a February press conference in Washington, DC.

The physician delivered a letter to Reagan, saying that "we are pleased to associate ourselves with you in drawing the attention of people across the nation to the humanity and sensitivity of the human unborn. You stand on firmly established ground." Signatories include former American College of Obstetricians and Gynecologists (ACOG) presidents Richard T.F. Schmidt, MD, and Fred Hofmeister, MD, and 24 other physicians.

The dispute remains unsettled, however, ACOG spokesman Ervin E. Nichols, MD, has performed a National Institutes of Health literature search and contends there is no legitimate scientific evidence showing that fetuses feel pain early in pregnancy. In fact, scientific literature suggests just the opposite, he says: the fetal spinal cord is not adequately covered until the fifth month of pregnancy, and the fetal cerebellum is not sufficiently developed until the seventh month of pregnancy. A sensation of pain is dependent upon these two processes, he says.

* * * *

Health Groups Fan "Smokescreen" of Cigarette Manufacturer

Twenty years after the now-famous Surgeon General's report linking smoking and disease, tobacco companies have decided to fight back.

In a multi-million dollar campaign to defend smoking, tobacco manufacturer, R.J. Reynolds Industries, Inc., is running advertisements in newspapers and magazines asking: "Can we have an open debate about smoking?," saying that not all scientific evidence indicates that smoking is hazardous.

At a February news conference in Washington, DC, three health organizations have launched their own counter-offensive. Leaders of the American Cancer Society, American Heart Association, and the American Lung Association called the Reynolds campaign "a smokescreen" by "a desperate industry."

"This is one of the most misleading and irresponsible advertising campaigns any of us in this room can remember," said Edwin B. Fisher Jr., of the American Lung Association. "It's like opening a debate as to the lethality of bullets."

The health hazards of smoking "have been questioned by vested interests but never repudiated by science," said Antonio M. Gotto, MD, a Houston cardiologist and current president of the American Heart Association. "We are appalled that an attempt is being made to reopen the case against cigarette smoking."

They also criticized the tobacco companies' use of mountain climbers, ballet dancers, skiers, and other athletes to sell cigarettes, saying they violate an industry code that advertising not show smokers engaged in physical activity "beyond that of normal recreation." The Tobacco Institute, a trade group, says these ads meet the code, adding that interpretation of their content is subjective.

Insiders note that manufacturers are getting nervous about the increasing unpopularity of the habit, and growing restrictions on where and when to smoke.

Rx Drug Ads Nixed by Consumers, CBS Finds

What is likely to be an influential report on direct-to-consumer advertising of prescription drugs was unveiled by CBS Television researchers in February. Its findings, presented to the medical community and the Food and Drug Administration, will be used to guide TV advertising policy once the FDA's moratorium is lifted.

The study's results are based on 40-minute in-home interviews with 1233 consumers and are projectible to the 77.4 million U.S. households believed to use prescription drugs. By knowing consumer attitudes about drugs, CBS can then suggest the most responsible and effective ad guidelines, researchers say.

The central conclusion is that consumers need more information about drugs. Nearly three-quarters of all interviewed households said they wanted to be better informed about drugs. Only one-third said they were well-informed about drug issues.

* * * *

Liver Transplants Next for Federal Funding?

The Reagan Administration has decided to recognize liver transplantation as a non-experimental procedure for children with biliary atresia and other rare congenital defects, thus opening the doors to reimbursement by federal programs such as CHAMPUS.

The decision is also expected to encourage states to change their reimbursement policies under Medicaid. Some states already reimburse for liver transplantation.

"This decision reflects the advances in medical science which offer new hope for children afflicted with biliary atresia," said Health and Human Services Secretary Margaret Heckler. "Lifting the experimental label is a significant advance."

Public focus on improved survival rates—resulting from Congressional hearings and a National Institutes of Health consensus conference—is credited with the government's change in position.

* * * *

NIH Warns Against Ultrasound Misuse

Diagnostic ultrasound should be used only when medically indicated and not administered routinely to all pregnant women, according to a report issued in February by a National Institutes of Health panel of physicians.

No actual adverse effects have ever been associated with ultrasound, the panel agreed. But "hypothetical risks" should not be ignored or overlooked, said panel chairman Fredric Frigoletto, MD, professor of obstetrics and gynecology at Harvard Medical School.

A Chronology of Health Legislation in the U.S., 1798-1983

1798 Congress established U.S. Marine Hospital Service (now the Public Health Service), financed by compulsory deductions of 20¢ a month from seamen's wages.

1818 Office of the Surgeon General established.

1877 First medical examiner system for public investigation of death begun in Massachusetts (abolished old English coroner system).

1887 Public Health Service opened one-room lab in Staten Island marine hospital to do research on bacteria, vaccines and quarantine techniques—forerunner of National Institutes of Health, 50 years later.

1908 Federal Workmen's Compensation law passed; Wisconsin led 10 states in 1911 in passing first state law; laws paved way for medical care coverage for occupational accidents or diseases.

1912 President Theodore Roosevelt (up for reelection) was first presidential candidate to endorse concept of national health insurance and wrote it into the Progressive Party's platform; it was supported by the American Medical Association (AMA). (See 1935 for AMA switch).

1915 Committee on Social Insurance (first of its kind in the U.S.) of the American Association for Labor Legislation drafted a model bill for compulsory medical care insurance and pressured states to enact government health programs; most intense opposition came from organized medicine in California and New York and from Samuel Gompers, AFL president; not one state passed legislation.

1917 65th Congress provided direct medical care in Public Health Service facilities to World War I veterans with service-connected disabilities; laws of 1922 and 1924 liberalized eligibility requirements; 1933 law extended medical and domiciliary care to all veterans of any war since 1897, regardless of whether disabilities were service-connected.

1918 Chamberlain-Kahn Act was first federal grant-in-aid program—for control of venereal disease; followed in 1921 by maternal and child health services grant.

1933 First example of federal funding for care of the medically indigent: Federal Emergency Relief Administration provided limited medical, dental and nursing services for 2½ years.

1934 New York passed the first special "enabling act" to exempt Blue Cross Plans from provisions of the state insurance code; most Plans were founded under enabling acts.

1935 Social Security Act passed to provide retirement & death benefits, a federal/state unemployment compensation system, federal grants to states in developing public health programs, and aid to dependent children, the blind & disabled. Employer/employee contributions began in 1937 with each contributing 1% of first $3,000 of annual wages.

Because of strong counter-pressure by the AMA and other political/economic factors, health insurance was not incorporated into the final draft of the SS Act, as it had been in many European nations (see "Around The World" box).

Wagner Act assured the rights of workers to organize and bargain collectively and established National Labor Relations Board.

Works Projects Administration constructed and improved local hospitals; Lanham Act of 1941 provided for wartime emergency building of hospitals, health centers and clinics—forerunners of Hill-Burton Act.

1936 Department of Agriculture made medical prepayment plans available to low-income farmers who were borrowing from the Federal Security Administration; program experience unsatisfactory and it was stopped in 1946.

1937 Railroad Retirement Act passed for railroad workers; similar to Social Security but amended to include survivors and dependents and to cover maternity and sickness benefits for disabilities on and off the job.

SOURCES: Back issues of *PERSPECTIVE* Magazine; *SOURCE BOOK OF HEALTH INSURANCE DATA* of the Health Insurance Association of America; *LEGISLATIVE ROUNDUP* of the American Medical Association; *MEDICAL CARE & HEALTH INSURANCE* by Joseph Follmann, Jr.; *BLUE CROSS SINCE 1929* by Odin Anderson; *REGULATION OF BLUE CROSS & BLUE SHIELD PLANS* by Robert Eilers, Ph.D., and various newspaper and magazine articles.

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1938 Cancer was the first of 10 National Institutes of Health . . . followed by heart, allergy and infectious diseases, arthritis and metabolic diseases, child health and human development, dental research, general medical sciences, mental health, neurological diseases, and eye.

Fair Labor Standards Act banned oppressive child labor and set minimum hourly wage at 25¢ (30¢ the second year and 40¢ the seventh year) and maximum work week at 44 hours (reduced to 40 the third year); applied only to interstate commerce; President Roosevelt declared it "the most far-sighted program for the benefit of workers ever adopted, except perhaps for the Social Security Act."

Federal Food, Drug & Cosmetic Act provided for regulation by the Food and Drug Administration (FDA) of new drugs and those currently being marketed.

National Health Conference proposed five-point national health program: (1) provision for general and public health, maternal and child health services; (2) construction of hospitals and health centers; (3) medical care for indigent and medically needy persons; (4) provision of general medical programs; (5) provision of certain forms of disability insurance.

1939 Family and monthly survivors' benefits added to Social Security; the word "insurance" introduced into the old-age provisions. Sen. Robert Wagner, with organized labor support, introduced first major bill (National Health Bill) aimed at creating a national health program; not passed, largely due to growing concern of a "Red takeover."

1940 First federal program for control of communicable diseases.

1942 President Roosevelt called for social insurance (including health) "from the cradle to the grave."

Rhode Island was first state to enact a compulsory disability compensation law; California followed in 1946, New Jersey in 1948, and New York in 1949.

National War Labor Board held to the wage freeze, but set precedent by approving increases in the form of fringe benefits . . . a major reason why private health insurance bloomed and flourished.

1943 First Wagner-Murray-Dingell Bill proposed to establish a comprehensive compulsory federal health benefit program added to Social Security; defeated in Congress by American Medical Association leadership.

Emergency Maternity and Infant Care Program, administered by U.S. Children's Bureau through state health departments, for wives and dependents of military men, was first national uniform program paying for health care using voluntary hospital, private practice system; program ended in 1949. (See 1956 CHAMPUS entry.)

1944 Public Health Service Act revised and coordinated existing legislation on the organization, staffing and programs of the Public Health Service.

1945 Harry Truman was first president to present an official administration proposal for national health insurance to Congress; it included a revised Wagner-Murray-Dingell Bill.

McCarran Act affirmed state regulation of insurance and declared federal anti-trust laws would be applicable to insurance only to the extent that it is not regulated by state law.

1946 Hospital Survey & Construction Act (Hill-Burton program) assisted states in constructing hospitals; 1954 amendment added long-term facilities, rehabilitation centers and outpatient departments; Hill-Harris amendments of 1964 set precedent for use of public funds to subsidize planning by voluntary health agencies.

No-fault auto insurance (including medical payments for the injured) first legislated in Saskatchewan, Canada; Puerto Rico followed in 1970; Massachusetts was first no-fault state in 1971.

1947 Taft-Hartley Act passed, permitting joint labor/management funds.

National Labor Relations Board ruled pensions and other employee fringe benefits are subject to bargaining.

First counter-proposal (by Sen. Robert Taft, Sr.) to compulsory medical care insurance would assist states to provide care for the indigent.

1948 National Labor Relations Board ruled—in a dispute between the United Steelworkers' Union and Inland Steel Co.—that the term "wages" includes pension and insurance benefits; U.S. Supreme Court upheld this ruling in 1949.

1949 President Truman attempted to coordinate federal services by forming the Federal Security Agency; President Eisenhower granted it cabinet status as the Department of Health, Education & Welfare in 1953, with Oveta Culp Hobby as the initial secretary.

1950 Social Security eligibility liberalized; farm, domestic and some self-employed workers included; federal/state matching funds provided for recipients' medical care. Employer/employee contributions increased to 1.5% of first $3,000 of annual wages.

I.S. Falk, then of Social Security Administration, proposed a government health insurance program limited to beneficiaries; it was the forerunner of Medicare 16 years later.

Federal Trade Commission set down trade practice rules governing advertising and promotion of mailorder insurance; in 1955 the National Association of (state) Insurance Commissioners promulgated an advertising code for health insurers.

1954 Federal Employees Group Life Insurance Act provided life, accidental death & dismemberment insurance to civilian government employees through private insurance companies. Federal Employees Health Benefits Program begun in 1960; now largest health insurance group in world with 2.8 million members covering 9.2 million people; 179 carriers handle coverage with Blue Cross and Blue Shield Plans accounting for 43% of total membership.

Social Security coverage extended to all self-employed except lawyers, doctors, dentists and other medical groups.

1955 Mental Health Study Act led to development of community-based programs as substitute for large, understaffed mental hospitals; Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963 aimed to develop 2,000 centers by 1975.

1956 Government health services extended to military dependents in civilian medical facilities; originally a military "Medicare" law, now called CHAMPUS—Civilian Health & Medical Program of the Uniformed Services; this coverage set something of a precedent for full Medicare program 10 years later.

Social Security benefits added for disabled workers 50 & over; women's eligibility age reduced to 62.

Massachusetts led the states in legislating state-required health benefits (for physically handicapped & mentally retarded); New York followed in 1965, and added mental/nervous conditions in 1968; 14 states had done so by 1970. California, Louisiana, North Carolina and Texas passed laws in the early 1970s requiring coverage of new-born infants from the moment of birth; in 1971, Wisconsin was first to require contracts to provide for treatment of alcoholism.

Canada passed Hospital Insurance & Diagnostic Services Act (implemented in 1958); provided federal cost-sharing with provinces; covered inpatient care, outpatient services; in 1966, Medical Care Act ("Medicare") provided for voluntary province-by-province state-sponsored medical-care insurance for physician services in home, office, hospital, etc.; in 1968, Report on the Cost of Health Services "blew the whistle on mounting health care costs"; in 1976, federal government placed ceiling on per capita rate of growth of federal contributions to health care costs.

1957 Forand Bill (not passed) proposed covering aged for expense of 60 days' hospital care, 120 days' nursing home care and surgical benefits; marked beginning of intensive political argument on health care for aged.

1958 Social Security added dependents of disabled beneficiaries.

1960 Kerr-Mills Bill (forerunner of Medicaid) provided federal matching funds for medical care of public assistance recipients; by 1965 all 50 states and the four jurisdictions had such programs. Bill also provided Medical Assistance for Aged, first federal program for those who were "medically indigent" but not eligible for public assistance.

Disability benefits extended to all age groups; men's eligibility age reduced to 62. Employer/employee contributions increased to 3% of first $4,800 of annual wages.

1961 King-Anderson Bill (not passed) set stage for Medicare Act by proposing 90 days of hospital care or 180 days of hospital/nursing home care, home nursing services and cost-sharing by patient for beneficiaries 65 and over.

First state enrollment plan offered in Connecticut to persons 65 and over under special enabling legislation allowing the pooling of risks by a group of insurance companies.

1962 Migrant Health Act provided federal funding for health services for migrants; Appalachian Regional Development Act of 1965 supported projects to provide comprehensive health care for the Appalachian poor.

1963 Maternal & child health Social Security Amendments of 1963, 1965 and 1967 assisted states and local health departments by paying up to 75% of the costs of care.

Health Professions Educational Assistance Act provided first federal subsidizing of health education; followed by Nurse Training Act of 1964, amendments of 1965, and Allied Health Professions Personnel Training Act of 1966.

1964 Economic Opportunity Act provided OEO funding for three neighborhood health centers in Boston, New York City & Denver; five others funded in 1965; 1966 amendment provided $50 million to develop Comprehensive Health Service Projects in urban and rural areas of poverty and inadequate health service.

1965 Heart Disease, Cancer & Stroke Amendments to Public Health Service Act created Regional Medical Programs to provide planning grants and operational grants for projects associated with the diseases listed in act; 55 RMPs were approved; however, program was replaced with Health Systems Agencies in 1974.

Solid Waste Act launched widespread program of waste handling research; Air Quality Act of 1967 authorized federal government to set tolerance standards for air pollution and to provide information on cost and methods of prevention.

1966 Medicare Act (Rep. Wilbur Mills' revision of King-Anderson Bill) went into effect, providing federal hospital insurance and supplementary medical insurance for beneficiaries 65 and over; coverage extended to interns and self-employed doctors; Medicaid replaced Kerr-Mills program with state/federal matching funds for nearly complete health coverage for poor. Employer/employee Social Security contributions increased to 4.4% of first $6,600 of annual wages.

Comprehensive Health Planning & Public Health Service Amendments (also known as Partnership for Health Act) attempted to reshape the nation's health system through federal grants for state and area-wide health planning and grants-in-aid to support health services.

1967 Early Periodic Screening, Diagnosis and Treatment Program (EPSDT) created to provide screening and health services for needy children.

Federal government assumed licensing and regulatory authority over clinical laboratories engaged in interstate commerce.

Age Discrimination in Employment Act became effective; applied only to employees aged 40 to 65, who were to receive same benefits as younger employees; 1978 amendment raised mandatory retirement age from 65 to 70.

1969 National Environmental Policy Act created Council on Environmental Control.

1970 Occupational Safety & Health Administration (OSHA) created to establish and enforce worker safety and health standards in business and industry.

Clean Air Act amendments established nationwide ambient air quality standards and motor vehicle emissions standards.

Family Planning Services & Population Research Act established nationwide program of family planning and research.

Medical Facilities Construction & Modernization amendments extended Hill-Burton program for three years over President's veto.

Comprehensive Drug Abuse Prevention & Control Act included scheduling of drugs and control of drug distribution.

1971 Comprehensive Health Manpower Training Act authorized $2.9 billion over three years for constructing and operating medical schools and to provide loans and scholarships for students in health care.

Nurse Training Act authorized $855.5 million over three years to aid schools and students of nursing.

Economic Stabilization Program (Cost of Living Council) initiated controls on prices (including hospitals) which continued until 1974.

National Cancer Act authorized $1.6 billion over three years for cancer research; 1974 Act modified the national cancer program and authorized $2.6 billion over three years.

1972 The largest set of Social Security amendments in U.S. history passed by 92nd Congress. They added 1.7 million disabled to Medicare eligibility and expanded Medicare and Medicaid benefits to include renal dialysis and kidney transplants, chiropractic, optometric services, care in mental institutions, etc.; Medicare beneficiaries could opt for benefits from a Health Maintenance Organization such as prepaid group practice, foundation for medical care or neighborhood health center; Professional Standards Review Organizations to review medical necessity, quality of care and cost of Medicare and Medicaid services. Employer/employee Social Security contributions increased from 5.85% of first $10,800 of annual wage in 1973 to 7.3% in 2011 (rate accelerated later—see 1983 entry).

Cost of living adjustment to disability benefits introduced.

Supplemental Security Income program created to federalize categorical public assistance for the aged, blind, and permanently and totally disabled.

Both presidential candidates (Nixon and McGovern) included broad national health insurance proposals in their party platforms.

1973 Health Maintenance Organization Act provided $375 million in federal subsidies over five years to prepaid group practices; all employers with 25 or more employees providing health insurance as a benefit were required to make HMO enrollment available where HMOs exist.

National 55-MPH speed limit adopted; 10 years later National Highway Traffic Safety Administration estimated 45,000 lives had been saved.

1973-75 90 separate bills dealing in some manner with national health insurance were introduced in 93rd Congress; none went beyond hearing stage.

1974 Employee Retirement Income Security Act (ERISA) signed into law; major thrust was regulation of employee pension plans, but also covered "welfare" plans providing benefits for health care, sickness, disability, death, unemployment, vacations, training programs, child care centers, prepaid legal services, scholarship funds, etc.

National Health Planning & Resources Act created system of national health policy, planning and development—then said to be the most significant national health law in 20th century; created Health Systems Agencies (HSAs) to influence supply of services, reduce surpluses and fill the gaps . . . to create appropriate balance of available services; eventually, there were to be 205 HSAs throughout the U.S.; essentially killed 7 years later (see 1981 entry).

Connecticut Hospice (New Haven) was first hospice in U.S.; Connecticut law required newly issued health insurance policies to include hospice coverage; in 1978 the state's Blue Cross & Blue Shield Plan was first in the nation to provide hospice coverage at home. Social Security amendment in 1982 provided for hospice reimbursement under Medicare effective Aug. 1, 1983.

National Arthritis Act expanded authority of the National Institute of Arthritis, Metabolism & Digestive

Diseases.

Hawaii was first state to enact comprehensive health insurance law.

Maine made catastrophic illness expense fund available; threshold was $1,000 per year per person for out-of-pocket health expense.

1975 Congressional Budget Office (CBO) established to prepare detailed five-year estimates on the cost to implement any public bill or resolution.

Maximum Allowable Cost (MAC) limitations established by HEW to determine allowances for specified durgs under Medicare, Medicaid and other federal programs.

Rhode Island catastrophic health insurance became effective—providing coverage for all residents after out-of-pocket expenses reached certain levels, based on their basic health plans.

Australia enacted Medibank as new national health insurance system—leaving the U.S. as last major holdout for passing an NHI program; but Medibank was abolished in 1979 in favor of the previous government-private fund combination.

1976 HMO Act amendments relaxed requirements for HMOs to qualify for federal support; 1978 amendments extended HMO assistance program for 3 years; in 1981 Congress all but eliminated requirements and modified the community rating system.

Health Professions Educational Assistance Act required medical school students who receive federal scholarships to serve a specified time in rural and inner-city areas; also required medical schools with teaching hospitals to provide more medical residencies in primary medicine.

Office of Inspector General created in HEW department to investigate fraud and inefficiency in all HEW programs.

National Consumer Health Information and Health Promotion Act set national goals for health information, stressed health education.

Tax Reform Act pushed prepaid legal insurance by exempting employer contributions toward group legal service plans from gross income—providing new competition with health insurance for fringe-benefit dollars; Shreveport Laborers' plan (1971) was one of first to be started.

Arizona catastrophic health coverage became effective; threshold was $1,000 out-of-pocket expense if total amounted to $5,000.

1977 During 95th Congress, Carter administration introduced hospital cost containment proposal designed to temporarily limit both revenues and expenditures of non-federal hospitals; no legislation adopted but most significant result was birth of the "Voluntary Effort," a nationwide voluntary program to contain health care costs sponsored by AMA, AHA, Blue Cross & Blue Shield Assns., Federation of American Hospitals, Health Industry Manufacturers Assn., Health Insurance Assn. of America, National Assn. of Counties and representatives of business and labor.

President Carter created President's Commission on Mental Health to review nation's mental health needs and programs and recommend improvements.

FDA moved to ban saccharin after Canadian tests showed it may cause cancer in animals; Congress blocked FDA action for 18 months.

Alaska became first state to require all physicians and hospitals to buy malpractice insurance from new state-owned corporation.

Medicare & Medicaid Anti-Fraud & Abuse amendments to the Social Security Act required uniform reporting of financial data by providers, upgraded criminal penalties for fraud and amended certain PSRO provisions.

1978 President Carter issued 10 principles for a "National Health Plan" which should: "assure that all Americans have comprehensive health care available to all . . . assure that all have freedom of choice in selection of (providers) . . . reduce unnecessary health care spending . . . offset additional public and private expenditures for improved health care benefits with greater efficiency in the system . . . involve no additional federal spending until fiscal 1983, then be phased in gradually . . . be financed through multiple sources, including government funding and contributions by employers and employees . . . should include a significant role for the private insurance industry . . . should increase the availability of ambulatory preventive services, attract personnel to underserved rural and urban areas, and encourage use of prepaid health plans . . . and should assure consumer representation throughout its operation." National health insurance was never enacted, but parts of Carter's 10 principles were implemented in the years that followed.

Civil Rights Act amended to prohibit sex discrimination on basis of pregnancy for all job-related programs, including health insurance and sick-leave benefits. In 1983 Supreme Court ruled that employee health plans covering dependents must provide the same pregnancy and childbirth benefits for wives of male workers as for female employees; U.S. Chamber of Commerce predicted this would cost business millions of dollars and would trigger "massive increases in the cost of health benefits."

1980 HEW split into two cabinet-level departments—Health & Human Services (HHS) and another for Education.

Tennessee law prohibits chiropractors from engaging in certain specified procedures, including prescription or administration of controlled substances, performing incisive surgery and performing X-ray therapy; Indiana and Utah followed in 1981. In contrast, California, Georgia and other states considered bills that would greatly expand the statutory scope of chiropractors' practices.

1981 Omnibus Budget Reconcilation Act mandated significant cuts in federal expenditures for health programs:

Health Planning: reduced the annual authorization for federal health planning program to $102 million (lowered to $64 million in 1982); raised the dollar thresholds for certificate-of-need (CON) reviews; permitted a state governor to request that federal designation and funding of HSAs located in that state be eliminated, provided state could meet requirements of the Health Planning Act without any HSAs.

PSROs: authorized HHS secretary to reassess performance of PSROs and to terminate 30% of those in operation; state Medicaid agencies were no longer mandated to have PSROs review cases.

Medicare: increased the Part B premium and Parts A & B deductibles, cut the nursing differential from 8.5% to 5%, eliminated coverage of alcohol detoxification, lowered Medicare inpatient hospital cost limits and instructed the Health Care Financing Administration to develop new rates for end-stage renal disease treatment and to encourage home dialysis.

Medicaid: home health care reimbursement was broadened to cover any service that can be obtained for less money at home than in an institution; Medicaid payments to states were reduced by 3% in 1982, 3% in 1983 and 4.5% in 1984. Arizona, the only state without a Medicaid program, entered into a capitated prepayment agreement with HCFA.

Health manpower: reduced the number of new first-year National Health Service Corps scholarships; mandated that people fulfilling NHSC obligations must accept Medicare assignment and provide services to Medicaid beneficiaries; eliminated medical school capitation payments and lowered authorization levels for student assistance programs. A special bill relating to foreign medical graduates also passed.

Health grants: President Reagan asked Congress to combine 26 federal categorical grant programs into two health block grants—one for health services and one for disease prevention. Instead, it placed 19 programs into four blocks: (1) maternal and child health care (including genetic research, adolescent pregnancy, sudden infant death syndrome, hemophilia, SSI for handicapped children, and lead-based paint poisoning); (2) preventive health and health services (including rodent control, water fluoridation, emergency medical services, home health, hypertension and rape crisis centers); (3) the community health center program was placed in its own primary care block grant; (4) alcohol and drug abuse and mental health were lumped into one block grant. Six programs were kept categorical (family planning, migrant health centers, venereal disease, childhood immunization, tuberculosis and primary care research).

President Reagan created National Commission on Social Security Reform to analyze financial condition of Social Security programs and the provision of benefits, including Medicare.

Reagan administration and Rep. Willis Gradison (R-O.) proposed providing Medicare recipients with vouchers to be used to purchase private health insurance.

Various pro-competition bills introduced on the premise that consumer choice and market forces, rather than regulation, should be relied on to control health cost inflation. Competition was urged among insurers, providers and delivery systems.

Ten states either enacted or amended existing child passenger protection laws mandating that children below a certain age or weight be protected with passenger restraint systems while being transported in vehicles.

Four states enacted the Uniform Determination of Death Act (drafted and endorsed by the AMA, American Bar Assn. and National Conference of Commissioners on Uniform State Laws) which recognizes the concept of "brain death" as medically acceptable for determining death.

A number of states passed laws dealing with low-level radioactive waste management and disposal (especially significant to health since such materials are used in lifesaving diagnostic and therapeutic procedures in nuclear medicine).

1982 New California law allowed insurance companies to negotiate alternative rates with selected providers, paving way for preferred provider organizations (PPOs). Essentially, a PPO could cut health care costs simply by prenegotiating lower rates with providers. Under Blue Cross of California's "Prudent Buyer Plan," hospitals are paid on flat per-diem basis regardless of service charges; physicians are offered a predetermined rate schedule. One insurer estimates that 80% of all insurance policies sold in California will be of PPO type within five years. PPOs also active in Colorado, Minnesota and Virginia.

Tax Equity and Fiscal Responsibility Act (TEFRA) provided Medicare recognition for any state hospital cost control system that meets certain federal standards, including equitable treatment of all payors; made Medicare secondary payor for employees aged 65-69 with employer-sponsored health insurance; brought federal employees under Medicare, and changed methods of hospital reimbursement under Medicare. TEFRA was voted down in less than a year and replaced with the 1983 prospective payment amendment, the most historic change in Medicare law since its passage 17 years ago—it provided for prospective reimbursement of hospitals based on their experience.

Health Care Financing Administration of HHS ruled, with the effect of law, that costs for care in freestanding surgery centers would be paid under Medicare.

President Reagan designated 1982 as the National Year of the Disabled to improve the quality of life for the nation's disabled.

1983 Social Security Amendments Act closely followed recommendations of the National Commission on Social Security Reform. When fully implemented, it is expected to infuse the SS retirement system with $169 billion through future benefit reductions and tax increases. Total Federal Insurance Contributions Act (FICA—which includes Medicare) tax rates to be paid by both employees and employers will be increased from 6.7% on a maximum taxable wage base of $35,700 for 1983 . . . to 7% on $37,500 in 1984, 7.15% in 1985-87 on wage bases from $39,000 to $42,300, 7.51% in 1988 on a wage base of $44,400, and 7.65% in 1990. (Future wage bases are estimated by the Social Security Administration and may be low.)

Other major changes include: making newly hired federal employees and elected federal officials subject to SS; state or local governments currently covered may no longer withdraw from the system.

Postponing the cost-of-living adjustment for 1983 from June to December, with all future adjustments in December; this is expected to save $40 billion over 7 years.

Increasing the normal retirement age (starting in the year 2000) from 65 to 67 in 2022 and beyond; those electing early retirement will receive lower benefits.

Making one-half of SS benefits subject to federal income tax (starting in 1984) if income totals certain amounts.

Reducing benefits for certain government employees who also receive pensions based on noncovered employment.

The amendments also made major revisions in hospital reimbursement under Medicare: Peer review organizations (PROs) were required to do what PSROs once did. A participating hospital must contract with a PRO by Oct. 1, if there is one in the hospital's area; *all* participating hospitals must do so by Oct. 1, 1984. Hospital reimbursement rates also to be set by diagnostic related groups (DRGs) with regional rates for urban and rural areas; gradually, over several years, a national urban rate and a national rural rate would be phased in for each DRG. Another amendment will reduce the rate of return on equity for proprietary hospitals to the rate of return on trust fund investments rather than the present 1.5 times that rate; eventually, the return on equity would be folded into the DRG rate.

Legislative proposals for health insurance for the unemployed included an entitlement program and another for a block grant to the states; passage of some kind of bill expected in 1983.

FIVE CHIROPRACTOR PLAINTIFFS petitioned the U.S. Supreme Court to review their antitrust case against the AMA. The petition argued that the U.S. Court of Appeals for the 7th Circuit failed to follow the high court's guidelines for antitrust actions involving ethical codes of professional associations and boycotts. The original jury trial in 1980-81 resulted in a verdict in favor of the AMA and other respondents. Last September, however, the U.S. Court of Appeals reversed the judgment and remanded the case for a new trial. The appeals court cited improper jury instructions and the improper admission of prejudicial evidence. The chiropractor plaintiffs now have asked the Supreme Court to review certain rulings by the appellate court that allegedly have the effect of granting new authority to medical societies to restrain competition and exclude chiropractors from hospitals.

In addition to the AMA, other defendants in the case are the American Hospital Assn., American College of Surgeons, American College of Physicians, Joint Commission on Accreditation of Hospitals, American College of Radiology, American Academy of Orthopaedic Surgeons, Illinois State Medical Society, and a number of individuals.

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State Health Legislation

Selected Highlights of Recently Enacted State Legislation

AMERICAN MEDICAL ASSOCIATION

ALCOHOLISM

Connecticut has enacted legislation providing for certification of alcoholism counselors. A certified alcoholism counselor is a person who, by virtue of special knowledge, training and experience, is uniquely able to inform, motivate, guide and assist alcoholics and those persons affected by problems related to the abuse of alcohol, and who has been certified by the state Alcohol and Drug Abuse Commission. The Alcohol and Drug Abuse Commission shall issue a certificate to any person who applies to be certified as an alcoholism counselor and who proves to the satisfaction of the Commission that 1) he is currently certified by the State Alcoholism Counselor Certification Board; or 2) he meets such other criteria as the commission shall prescribe by regulation. The Alcoholism Counselor Certification Board shall grant a certificate without payment of an application fee or an examination to any person who, not later than one year from the effective date of this act (July 1, 1983) presents evidence to the Board that on the effective date he has been employed as a provider of alcohol counseling services for a minimum of three years in a state operated program for the treatment of alcohol abuse, meets all the application requirements of the Board and presents payment of the certification fee. (H.B. 6440)

CHIROPRACTIC

Iowa, Minnesota, Nebraska, Nevada and **New York** have amended their laws relating to chiropractic.

Iowa has amended its statutory definition of the scope of chiropractic practice to define chiropractors as "persons who treat human ailments by the adjustment of the neuromusculoskeletal structures, primarily by hand or instrument, through spinal care." Prior to amendment, the law had defined chiropractors as "persons who treat human ailments by the adjustment of the musculoskeletal structures, primarily spinal adjustments by hand, or by other procedures incidental to said adjustments limited to heat, cold, exercise and supports . . . but not as independent therapeutic means."

The law, as amended, authorizes within the scope of chiropractic practice "utilizing differential diagnosis and procedures related thereto, withdrawing or ordering withdrawal of the patient's blood for diagnostic purposes, performing or utilizing routine laboratory tests, performing physical examinations, rendering nutritional advice, utilizing chiropractic physiotherapy procedures . . . . However, a person engaged in the practice of chiropractic shall not profit from the sale of nutritional products coinciding with the nutritional advice rendered." The law also provides that "a chiropractor using the additional procedures and practices authorized by this Act shall be held to the standard of care applicable to any other health care practitioner in this state."

The law also adds "nutrition and dietetics" to the subjects included in the examination which must be passed by an applicant for a license to practice chiropractic. (S.B. 474; Iowa Code §§151.1 et seq.)

Minnesota has amended its law to create a legislative study commission to "study and report on the utilization of venipuncture for diagnostic purposes in the practice of chiropractic and medicine." The study commission (consisting of four state legislators, two M.D.s and two chiropractors) is to report its findings to the legislature on October 1, 1984. (S.B. 159; Minn. Stat. §148.10)

Nebraska has amended its statutory definition of the scope of chiropractic practice to define chiropractic as "being one or a combination of the following, without the use of drugs or surgery: (1) the diagnosis and analysis of the living human body for the purpose of detecting ailments, disorders, and disease by the use of diagnostic x-ray of the axial skeleton excluding the skull, physical and clinical examination, and routine procedures including urine analysis, or (2) the science and art of treating human ailments, disorders, and

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State Health Legislation Report, (Vol. II, No. 4, 1983).

disease by locating and removing any interference with the transmission and expression of nerve energy in the human body by chiropractic adjustment, chiropractic physiotherapy, and the use of exercise, nutrition, dietary guidance, and colonic irrigation." Prior to amendment, the law had provided that "the following classes of persons shall be deemed to be engaged in the practice of chiropractic: (1) persons publicly professing to be chiropractors, or publicly professing to assume the duties incident to the practice of chiropractic, and (2) persons who treat human ailments by the adjustment by hand of any articulation of the spine." (L.B. 142; Neb. Rev. Stat. §71-177)

Nevada has amended its chiropractic law to provide for a statutory definition of malpractice. "Malpractice" is defined to mean "failure on the part of a chiropractor to exercise the degree of care, diligence and skill ordinarily exercised by chiropractors in good standing in the community in which he practices." (S.B. 80; Nev. Rev. Stat. §634-2 et seq.)

New York has amended its law to expand the scope of x-ray use by chiropractors. The New York law, as amended earlier this year, allows chiropractors to use x-ray for "the detection of structural imbalance, distortion, or subluxations in the human body." Prior to amendment, the law had permitted chiropractors to use x-ray only upon persons over the age of 18, with the area of such x-ray exposure not to extend below the level of the top of the first lumbar vertebra. (A. 3337-B; N.Y. Educ. Law §§6551(a) and (b))

CONFIDENTIALITY

Connecticut now provides for a privilege between a victim and a "battered women's counselor" or a "sexual assault counselor." Such a counselor is prohibited from disclosing any confidential communications made to such counselor by a victim in any civil, criminal, legislative, or administrative case or proceeding, unless the victim who made the confidential communications waives the privilege. The location of the battered women's center or rape crisis center and the identity of the counselor may not be disclosed under any circumstances in any civil or criminal proceeding.

When a victim has been adjudicated incompetent or is deceased, the guardian of the victim or the administrator of the victim's estate may waive the privilege. A minor may also knowingly waive the privilege unless the court decides that the minor lacks the capacity to knowingly waive. In the latter instance, the minor's parent or guardian may waive the privilege on the minor's behalf provided that the parent or guardian is neither the defendant nor has a relationship with the defendant, giving him or her an interest in the outcome of the proceeding.

The privilege does not apply:

1. In matters of proof concerning chain of custody of evidence;
2. In matters of proof concerning the physical appearance of the victim at the time of the injury; or
3. When the battered women's counselor or sexual assault counselor has knowledge that the victim has given perjured testimony and the defendant or the state has made an offer of proof that perjury may have been committed. (H.B. 6290)

Illinois has also amended its law concerning confidentiality of statements made to rape crisis personnel. The law will now protect against public disclosure statements in cases where indecent liberties with a child are involved, in addition to the protections already given to victims of rape and deviate sexual assault.

Under the law, "rape crisis counselor" is defined as one who is employed in any organization or association defined as a rape crisis organization, who is a psychologist, social worker, or volunteer who has undergone forty hours of training and is under the control of a direct services supervisor of a rape crisis organization. A rape crisis counselor may not disclose any confidential communication or be examined as a witness in any civil or criminal proceeding about any confidential communication without the victim's consent. Knowing disclosure of a confidential communication by any rape crisis counselor constitutes a misdemeanor. "Confidential communication" is defined as any communication between an alleged victim of rape, deviate sexual assault, incest, aggravated incest, indecent liberties with a child or an attempt to commit any such offense, and a rape crisis counselor in the course of providing information, counseling and advocacy. It includes all records kept by the counselor or by the organization in the course of providing services to an alleged victim concerning the alleged victim and the services provided. (S.B. 204; Ill. Rev. Stat. ch. 110, §8-802.1)

DRUGS

Drug Substitution

In **Connecticut** a new law provides that during the period from July 1, 1983 to June 30, 1984, the insurer or third party prescription program administrator of a prescription drug benefit program toward which the state pays any portion of the premium shall pay a pharmacist a professional dispensing fee of twenty-five cents per prescription, in addition to any other dispensing fee, for substituting a generically equivalent drug product for the drug prescribed by a licensed medical practitioner for a person enrolled in such prescription drug benefit program. (H.B. 5322)

A new **Florida** law permits an institutional formulary system to be adopted in a Class II institutional pharmacy. "Institutional formulary system" means a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a pharmacist practicing pharmacy in a Class II institutional pharmacy. "Class II institutional pharmacies" are institutional pharmacies which employ the services of a registered pharmacist who, in practicing institutional pharmacy provides dispensing and consulting services on the premises to patients of that institution for use on the premises of that institution. An institutional formulary system may be adopted with approval of the medical staff. An institution operating under the formulary system shall establish policies and procedures for the development of the formulary system in accordance with the joint American Hospital Association and American Society of Hospital Pharmacist standards for utilization of a hospital formulary system. Under prior law, "using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed" was grounds for disciplinary action, except in the case of generically equivalent drug products. (H.B. 676; Fla. Stat. §§465.003, -.016, -.019)

HEMOPHILIA

Hawaii has enacted a law to establish a financial assistance fund for persons suffering from hemophilia who require hemophilia-related medical care and treatment, but who are unable to pay the entire costs of such medical care and treatment. The duty to administer the law is delegated to the State Department of Health, which also has the responsibility to establish standards of eligibility for persons applying for assistance. (H.B. 114)

MATERNAL CARE AND BENEFITS

The **Connecticut** Commissioner of Health Services is directed to contract annually with local providers of health services to provide outpatient maternal and infant health services to needy pregnant women and infants up to age eighteen months. Eligibility is limited to families having an income equal to or less than one hundred eighty-five percent of the poverty level as measured by the Federal Office of Management and Budget poverty guidelines for nonfarm families, to those who are not eligible for medical assistance, and to those lacking private third party health insurance. The local provider is to determine eligibility for services, with the contracts including criteria for making such a determination.

Services provided under the contracts will consist of outpatient prenatal, postpartum and infant health care, including, at a minimum:

1. routine standard screening;
2. diagnostic services, including routine office laboratory procedures;
3. outpatient treatment services; and
4. preventive services; including prenatal and infant vitamins, nutrition services, health education and immunizations. (S.B. 2015-X)

MEDICAID

Connecticut has enacted a law establishing a Medicaid Cost Containment Study Commission. The Commission, in consultation with the Commissioner of Income Maintenance, must select an independent evaluator to analyze the existing medical assistance program and determine cost-effective measures which can be implemented, including consideration of the financial ability of individuals to contribute to the cost of the care of their adult relatives in nursing homes in accordance with federal law or regulation. Special emphasis is to be given to hospital inpatient and outpatient services and long-term care, as these areas comprise the majority of Medicaid expenditures. (H.B. 8008-X)

MEDICAL RECORDS

Connecticut has declared that any person who furnishes health care services shall supply to a patient upon request complete and current information possessed by that provider concerning any diagnosis, treatment and prognosis of the patient. Upon a patient's written request, a provider must furnish to the patient at a reasonable cost, a copy of the patient's health record, including but not limited to x-rays and copies of laboratory reports, prescriptions and other technical information used in assessing the patient's health condition.

If a provider reasonably determines that the information is detrimental to the physical or mental health of the patient, or is likely to cause the patient to harm himself or another, he may withhold the information from the patient. The information may be supplied to an appropriate third party or to another provider who may release the information to the patient. If disclosure of information is refused by a provider, any person aggrieved thereby may petition the superior court for the judicial district in which he resides for an order requiring the provider to disclose the information. The court will issue the order requested unless it determines that such disclosure would be detrimental to the physical or mental health of the person or is likely to cause the person to harm himself or another. These provisions do not apply to any information relative to any psychiatric or psychological problems or conditions.

A copy of the patient's health record, including but not limited to x-rays and copies of laboratory reports, prescriptions and other technical information used in assessing the patient's condition must be furnished to another provider upon the patient's written request. The patient will bear the reasonable costs of furnishing the information. (H.B. 5908)

Hawaii has adopted a resolution to urge all medical facilities in the state to retain all medical records until the legislature has the opportunity to act on this issue in the 1984 Regular Session. There is currently no state statute requiring the retention of medical records. (H. Res. 460)

New York has amended its public health law to provide that long term care facilities may not restrict or prohibit access by "records access ombudsmen" to the medical or personal records of any patient or resident, if the patient or resident or committee for an incompetent patient or resident has given express written consent to such disclosure. In the case of medical records, disclosure may be exclusive of the physician's personal notes, and access may be limited to certain times as delineated by regulation. (A.B. 6554-A; N.Y. Pub. Health §2803-C(3)m;. Soc. Serv. Law §§461-1, -4)

OPTOMETRY

So far this year, three states (**Colorado, New York** and **Virginia**) have enacted statutory provisions authorizing the use of topical pharmaceutical agents for diagnostic purposes by optometrists, bringing to 38 the total number of states which have such laws.

One approach, illustrated by the **New York** law, provides that the State Commissioner of Education, subsequent to consultation with the State Commissioner of Health, shall "specify by regulation the drugs which may be used in the practice of optometry, provided that the use of such drugs is limited (a) to topical application to the surface of the eye and (b) to diagnostic examination of the eye." The law further requires the Commissioner of Education to "establish by regulation educational and examination requirements for purposes of approving and certifying optometrists to use such drugs." (A. 6813; N.Y. Educ. Law §7101)

The more typical approach to use of diagnostic pharmaceutical agents by optometrists is reflected in a **Virginia** law, which sets forth specific drugs and the maximum strengths of those drugs which may be utilized by optometrists. The statute further requires optometrists, before utilizing diagnostic pharmaceutical agents, to "complete successfully a Board [of Optometry] approved course in general and ocular pharmacology as it relates to the practice of optometry which shall consist of at least fifty five classroom hours, including a minimum of fifteen classroom hours in general pharmacology, twenty classroom hours in ocular pharmacology and twenty classroom hours in clinical laboratory."

It also requires optometrists, before utilizing diagnostic pharmaceutical agents, to "pass a Board administered, performance-based examination on general and ocular pharmacology designed to test knowledge of the proper use, characteristics, pharmacological effects, indications, contraindications and emergency care associated with the use of diagnostic pharmaceutical agents." (S.B. 221; Va. Code §§54-386.1, -.2)

PODIATRY

California and **Nebraska** have recently amended their laws to expand the scope of practice of the profession of podiatry.

In **California**, the law as it stood before amendment defined podiatry as the diagnosis, medical, surgical, mechanical, manipulative, and electrical treatment of the human foot, including the nonsurgical treatment of the muscles and tendons of the leg governing the functions of the foot. As amended, the law now defines podiatry to include the diagnosis, medical, surgical, mechanical, manipulative, and electrical treatment of the ankle and all tendons that insert into the foot. The law as amended does specify, however, that surgical treatment of the ankle and tendons at the level of the ankle by a podiatrist must be performed only in a licensed general acute care hospital and only by podiatrists certified by the State Podiatry Examining Committee to perform such treatment. (A.B. 563; Cal. Bus. & Prof. Code §§2472, 2473)

Nebraska has amended its statutory definition of the practice of podiatry to eliminate the prohibition against podiatrists amputating the foot or toes or removing all of any bone of the foot except the distal phalanges. As amended, the law now permits podiatrists to perform these acts, prohibiting only the amputation of the forefoot. (L.B. 541; Neb. Rev. Stat. §71-173)

The Role of Profit in Medicine

AMA CENTER FOR HEALTH POLICY RESEARCH

The number of proprietary hospitals has been growing at a rapid pace increasing by 14 percent from 1981 to 1982. This change has resulted in a 12 percent increase in the number of proprietary beds. By the end of 1982, more than 10 percent of all hospitals were proprietary in nature and proprietary interests controlled 11 percent of all hospital beds. Health analysts have predicted that by 1990, proprietary organizations will control 20 percent of the hospital market.

This shift in the structure of the hospital industry has generated considerable interest in its effects on medical practice. This report summarizes the:

- distribution of physicians with primary admitting privileges in proprietary and nonproprietary hospitals by specialty, sex, years of practice, type of practice, and census region; and
- average income, hours worked, hospital utilization, and time spent with patients for physicians with primary admitting privileges in proprietary and nonproprietary hospitals.

The data are drawn from the AMA's second quarter 1983 Socioeconomic Monitoring System (SMS) survey.

Distribution of Physicians in Proprietary and Nonproprietary Hospitals

One perspective for gaining insight into the influence of proprietary organizations on physicians is to compare certain characteristics of physicians in proprietary and nonproprietary hospitals. This report compares two groups of physicians: those who admit their patients primarily to proprietary hospitals with those who admit their patients primarily to nonproprietary hospitals. *Data analyzed, but not shown in any of the following tables, indicate that nearly one out of every seven physicians (13.9%) with hospital admitting privileges admit their patients primarily to a proprietary hospital. In contrast, 86.1 percent of physicians with hospital admitting privileges have their principal privileges in a nonproprietary hospital.*

Table 1 reports the distribution of physicians within proprietary and nonproprietary hospitals by specialty, sex, years of practice, type of practice, and census region. Examination of these data reveals that the specialty distribution of physicians in proprietary and nonproprietary hospitals is not uniform. Only 10.4 percent of the physicians who work primarily in a proprietary hospital are general and family practitioners. This compares to 16.2 percent for those in nonproprietary hospitals. In contrast, there is little difference in the distribution of medical and surgical specialists in proprietary and nonproprietary hospitals.

In proprietary hospitals there is a greater percentage of female physicians than in nonproprietary hospitals. For proprietary hospitals, 10.4 percent of the physicians are female compared to only 5.7 percent for the nonproprietary hospitals.

Proprietary hospitals have a larger proportion of physicians with less than 5 years experience than do nonproprietary hospitals. Over one quarter (27.8%) of the physicians who work in proprietary hospitals have been in medical practice less than 5 years. By comparison, less than one fifth (18.6%) of the physicians who work in nonproprietary hospitals have been practicing less than 5 years.

Table 1 indicates that the distribution of solo and nonsolo physicians in proprietary and nonproprietary hospitals is almost identical. Approximately thirty percent of the physicians (29.8 and 28.4) that admit their patients to either a proprietary or nonproprietary hospital are solo practitioners.

Proprietary hospitals have grown most rapidly in the southern and western census regions. The distribution of physicians in proprietary settings follows closely the geographic distribution of these hospitals. As Table 1 shows, the majority of physicians with their principal privileges in proprietary hospitals are located in the southern and western census regions (48.6% and 31.9% respectively).

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The AMA Center for Health Policy Research directs the Socioeconomic Monitoring System in cooperation with the AMA Division of Survey and Data Resources.

Table 1

DISTRIBUTION OF PHYSICIANS IN PROPRIETARY AND NONPROPRIETARY HOSPITALS BY SPECIALTY, SEX, YEARS OF PRACTICE, TYPE OF PRACTICE, AND REGION, 1983*

	Proprietary Hospitals	*Nonproprietary Hospitals*
SPECIALTY		
General and Family Practitioners	10.4	16.2
Medical Specialists	22.9	25.5
Surgical Specialists	31.3	31.4
Other Specialists	35.4	26.9
SEX		
Male	89.6	94.3
Female	10.4	5.7
YEARS OF PRACTICE		
Less than 5 years	27.8	18.6
5-14 years	36.1	34.6
15-24 years	16.0	22.7
25 or more years	20.1	24.1
TYPE OF PRACTICE		
Solo	29.8	28.4
Non-solo	70.2	71.6
REGION		
Northeast	12.5	19.4
North Central	7.0	27.1
South	48.6	31.6
West	31.9	21.9

*Sample includes only physicians with hospital admitting privileges.

Table 2

PHYSICIAN AVERAGE INCOME, EXPENSES, HOURS WORKED, HOSPITAL UTILIZATION, AND TIME SPENT WITH PATIENTS BY TYPE OF HOSPITAL, 1983*

	Proprietary Hospitals	*Nonproprietary Hospitals*
INCOME AND EXPENSES**		
Net Income	$112,400	$113,000
Practice Expenses	85,100	82,100
HOURS WORKED PER WEEK		
Total	57.0	57.9
Office	27.0	26.7
Hospital	9.5	10.8
HOSPITAL UTILIZATION		
Patients Discharged Per Week	4.3	5.0
Length of Stay (Days)	6.4	5.7
TIME SPENT WITH PATIENTS		
Minutes per Hospital Visit	28.6	28.4

*Sample includes only physicians with hospital admitting privileges.
**Income and expense data are for 1982.

Physician Practice Characteristics by Type of Hospital

As noted, there has been considerable interest in the influence of proprietary hospitals on physician practice characteristics. Table 2 reveals that physicians whose primary admitting privileges are in proprietary hospitals had average net incomes of $112,400 in 1982. (Note: net income represents earnings after expenses but before taxes.) This was slightly less than the $113,000 that physicians in nonproprietary hospital settings earned. There was also little difference in practice expenses between these two groups of physicians. Physicians whose principal admitting privileges were in proprietary hospitals had $85,100 in practice expenses while physicians with their principal admitting privileges in nonproprietary hospitals had $82,100 in practice expenses.

Physicians with primary admitting privileges in proprietary hospitals, on average, work almost an identical number of total hours per week as physicians with privileges in nonproprietary hospitals, 57.0 and 57.9, respectively. Likewise, physicians in proprietary hospitals spend virtually the same amount of time in the office (27.0) as do their nonproprietary counterparts (26.7). In contrast, nonproprietary hospital physicians spend relatively more time on hospital rounds than physicians in proprietary hospitals, 10.8 hours versus 9.5 hours, respectively.

The similarity between physicians with principal admitting privileges in proprietary and nonproprietary hospitals can also be observed by examining patterns of hospital utilization and time spent with patients. As shown in Table 2, physicians in nonproprietary hospitals discharge, on average, 5.0 patients per week compared to 4.3 patients per week for physicians in proprietary hospitals.

Overall, Table 2 reveals that patients of physicians in proprietary hospitals have a slightly longer length of stay than patients of physicians in nonproprietary hospitals. Patients of physicians in proprietary hospitals stay an average of 6.4 days while patients of nonproprietary hospital physicians stay 5.7 days. The amount of time spent with patients for these two groups of physicians, however, is nearly identical, 28.6 minutes per hospital visit compared to 28.4 minutes.

In summary, while there are some differences between physicians whose principal privileges are in proprietary and nonproprietary hospitals, overall these differences appear small. Perhaps as proprietary hospitals continue to grow, differences in their physician populations will become more apparent, but at this time, these differences are not evident.

— *The second annual core survey of the Socioeconomic Monitoring System (SMS) consisted of interviews with 3,951 physicians. The overall response rate was 61.8 percent.*

The President's Page

Deceit and Compromise

The All Payor Prospective Payment Plan, by this time, has not only become an important bill designed to address the problem of rising health care costs, but has also become an emotional issue involving credibility, power politics, and the favoring of corporate over public interests. The proposed solution is certainly controversial and deserved careful and deliberate debate by all interested parties so that an effective solution to the problem would result. The proponents, however, in their zeal to push through Senate Bill No. 61, have compromised their own credibility. Big business and insurance have seized upon what they perceive as a potential hospital shortfall from low medicare payments, and have tried to convert it to a windfall of increased corporate profitability through the all payor system. They have continued to push through their plan as a product of consensus by all parties involved with health care, but in fact they have excluded all but proponents in its design. The cost commission, a politically appointed body concerned with maintaining and enhancing its regulatory powers, has resorted to the same ploy of seeking cooperation in the media while pursuing its own plan with its partners in big business and insurance. Finally, the co-chairperson of the Public Health Committee has gone so far as to publicly deny that any opposition even exists to some of the bill's provisions, in spite of contrary evidence and testimony.

It would be appropriate to repeat some of the CSMS objections to the original Bill:

1. It did not ensure complete confidentiality to patient, physician and hospitals.
2. There was no guarantee of an appropriate data base on which to establish DRG allocations of dollar amounts.
3. There was no assurance that the Commission would use the federally designated PRO, and could indeed create their own.
4. The hospitals had no right to appeal the Commission's decisions on the DRG groupings.
5. There was no effective professional monitoring and control of the system's impact upon the availability and quality of appropriate hospital care.

The groundswell of opposition prompted the Governor to call in the concerned parties and to demand that they hammer out a compromise bill. Unable to reach a reasonable compromise, the Public Health Committee bowed to political arm-twisting and voted out of committee a bill essentially the same as the one originally proposed and authored by the consortium of the business community and the Health and Hospital Commission. The threat that this bill presents in terms of unbridled control and government regulation of health care, the threat that it presents to the quality and availability of hospital care, and the absence of any evidence that it will indeed provide significant cost containment, is of major concern to physicians, hospitals, and patients alike. We may not have the financial resources to match the business and industrial complex to lobby our position. We may not have the political connections and clout that the Health and Hospitals Commissioner has as a former legislator. Nevertheless we do have enough influence as physicians in our communities to seek not only the direct help of our own legislators in opposing it, but in asking for the cooperation and support of all of our patients to do the same as well. And win or lose, we can also inform our patients before November, which of their elected representatives have voted to lower the value of their private health insurance, and to undermine the quality of their hospital care.

Daniel W. Doctor, M.D.
President

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Reflections from the Dean's Office

Marketable Skills or an Education?

ROBERT U. MASSEY, M.D.

In a recent University of Connecticut convocation held to honor former President Homer D. Babbidge, President DiBiaggio spoke of challenges for the future of university education:

"Perhaps one of the most serious is the growing predisposition of our entering students to focus on specific job or career preparation." He went on to affirm "—the certain knowledge that no one's long term interest is best served by this approach—not society's, not employers', and most importantly to us—not the student's."

This is the ancient faith of the teacher; today the light of that faith is burning low, and some, despairing of making converts and weary from seeking for any who will even listen, have gone over to the other side, to the side of the trainers. There are so many gadgets to learn about in a technological civilization, so many skills to acquire, so many competitors to out-guess and outmanueuver, so much money to be made that taking time for an education is an unaffordable luxury, even supposing it had any special appeal. When you think of it, the appeal of learning may be little more than a seduction to a kind of self-indulgence, quite out of place in the world of technology, corporate structures, and electronic games.

The old faith, however, refuses to die; it has been around long enough to be part of us, and at other times when the number of its disciples have been reduced to a remnant, society has found ways of protecting them. There have always been academies, libraries, monasteries, universities, large and small citadels of learning preserved by society to assure its salvation, or at least its respectability.

In medical education we have fallen into the habit of imagining the future and then trying to design educational programs that "will prepare our students for medical practice in the 21st century." We all think and talk that way at times, but that turns quickly into a kind of "specific job or career preparation" that President DiBiaggio referred to. Even if we were to be successful in accommodating our courses of study to the biological revolution, the explosion in technology, the aging of our population, the excessive numbers of physicians, the prospective payment systems, and the commercialization of medicine, the enterprise would not work. Beyond five to seven years the future is not knowable and any description of it is almost certain to be wrong. The future is more than the way things will be, it is also the values we shall come to attach to them. That makes for an impossible set of variables, shaky ground upon which to build an education or even to design part of a curriculum. It is enough to learn something about the present and the past that has led up to it; enough to get an education in the liberal arts and sciences, and to learn one of two things well; enough for the medical student to learn human biology and the methods of clinical medicine and to learn them very well. For better or worse, the future will most certainly take care of itself; how well it does will depend a little on how we manage the present and understand the past, but more on matters which now we only "see through a glass darkly."

What then should we be telling our students about medicine? Everything, of course, but especially we should tell them to pay more attention to their patients and less to themselves; we should not be ashamed to tell them that medicine is first of all a moral vocation with a call to perfection and that it is a special privilege to have received that call, never mind from where; we should remind them that medicine is more than technology, although that is part of it, more than science although it depends upon it, and that it is never a business, although right now almost everyone is trying to make it into one. Tell them never to call it the health care industry and never to speak of profitability or their market share; if they have been liberally educated they will understand the power embedded in words like those. Words like vocation, obligation, duty, commitment, respect, compassion, and selflessness have even more power, but they need to be spoken first and mentioned often without embarassment. They recur over and over in the course of a liberal education; they are the serious soul of liberal learning saving it from mere pedantry and luxurious self-indulgence, and making it the best kind of baggage to carry into the future.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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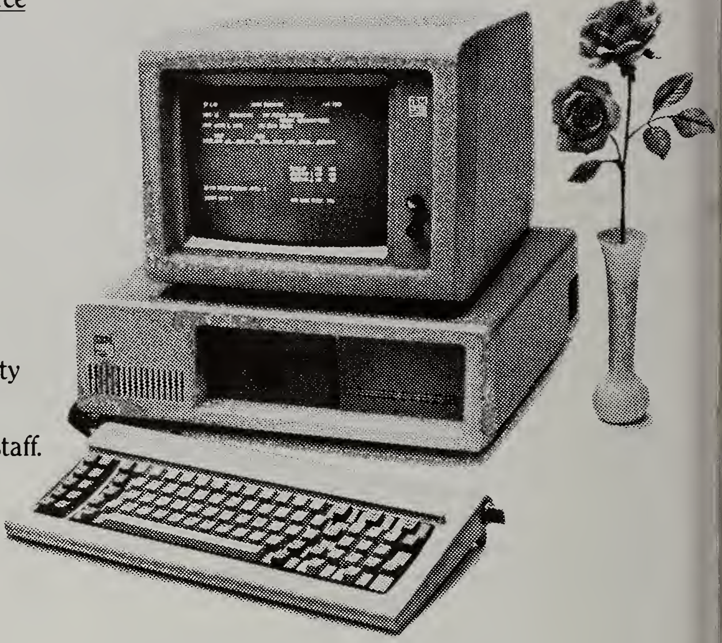

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Abortion 1984: The Controversy Continues

JOSEPH M. HEALEY, J.D.

Various attempts to provide a definitive legal resolution to the bitter abortion debate within our society have been unsuccessful. Neither legislative enactments nor judicial decisions have been able to produce broad-based agreement about what our societal policy ought to be. The legal framework for analyzing the abortion issue was set forth in the landmark Supreme Court decisions of *Roe v. Wade* and *Doe v. Bolton* in 1973. Among the most recent cluster of abortion cases reviewed by the Court was the case of *City of Akron* v. *Akron Center for Reproductive Health.* [1] In it, the Court was given an opportunity to reassess its commitment to the guidelines it recognized eleven years ago. This case provides us a good opportunity to review the current state of abortion law.

At issue in the Akron case was the constitutionality of several sections of the Akron city ordinances regulating abortion. Among the contested provisions were: 1. a requirement that all abortions after the first trimester be performed in a hospital; 2. a requirement that parental consent or court approval be obtained before an abortion could be performed on an unmarried minor under 15; 3. a requirement that the physician inform the patient of the status of her pregnancy, the development of her fetus, the date of possible viability, the physical and emotional complications that may result from abortion, the availability of agencies to provide her with assistance and information with respect to birth control, adoption, and childbirth, and the particular risks of her pregnancy and the abortion techniques to be employed; 4. a 24-hour waiting period between signing a consent form and having the abortion performed; and 5. a requirement that fetal remains be disposed of in a humane and sanitary manner. The District Court upheld 1, 4 and part of 3 while finding 2, 5 and part of 3 unconstitutional. The Court of Appeals affirmed much of the District Court's decision, except that it found that the only section constitutionally permissible was 1. The case was then appealed to the United States Supreme Court. In a 6-3 decision, the United States Supreme Court reaffirmed its commitment to the guidelines set forth in Roe and Doe, applied those principles to the Akron ordinances, and held that all provisions were unconstitutional.

At the center of the Supreme Court's analysis of the abortion issue is the concept of the "trimester trilogy." The Court previously held, and in the Akron case reaffirmed, that there exists a constitutional right to privacy which is sufficiently broad to encompass the decision of a woman and her physician to terminate a pregnancy. This right is not absolute but may be outweighed by a compelling state interests. Two state interests have been recognized by the Court: the protection of maternal health and safety and the protection of the actual or potential life of the fetus. These interests are recognized as compelling at different points in the pregnancy. Maternal health and safety becomes a compelling state interest at the point at which performance of the abortion involves significant health risks to the mother. At such a point, which the Court has described as occurring at approximately the end of the first trimester, the state is entitled to regulate abortion to protect the health of the woman. The second interest becomes compelling at fetal viability, the point at which the fetus possesses the capacity for meaningful existance independent of the mother. At such a point, the state may regulate abortion and even proscribe abortion in the name of protecting the life of the fetus. There emerges a framework of acceptable state regulation of the abortion decision depending on the stage of the pregnancy and the extent to which the state interest has become compelling. During the first trimester, neither state interest is compelling. During the second trimester, the state may regulate only to assure protection of maternal health and safety. During the period subsequent to viability, the state may regulate to protect the acutal or potential life of the fetus. However, abortion is permitted at any time in the pregnancy to preserve maternal life or health.

Further discussion will continue next month.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

REFERENCES

1. 51 LW 4767 1983.

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Editorial

Mayhem on the Commons

Can the medical commons, at least as we know it, last much longer? Cornerstones are eroded. Borders have been gerrymandered. Unspoken treaties, which provided the glue that kept it all together, have been broken or forgotten. Calls are heard to do away with the licensing of physicians and open the commons to everyone regardless of education or training.

It has never been so crowded. The predicted glut of physicians has occurred on schedule with more on the way. The number of non-medical practitioners has increased exponentially with old adversaries being joined by former old allies. The State by legislative fiat, continues to benevolently bestow the right to practice medicine on certain of its citizens. They are thus able to bypass the rigors and expense of a medical education.

It has never been so competitive. Numbers alone would assure this but the rivalry is being fueled by the federal government and industry. Both political parties have endorsed, as public policy, the concept that the health care problems of today would be cured by increasing competition in medicine. Serving as cheer leaders for this plan but with ideas of their own, the business coalitions are now demonstrating their primary concern with cost control with little corresponding concern with access and quality. They speak of preferred providers, volume discounts and stricter peer review with economic penalties—a scenario guaranteed to turn the medical commons into a full-fledged battlefield.

One of the longest running battles on the green has been between ophthamology and optometry. In this issue of the *Journal,* an optometrist and a third year medical student at Farmington, David D. Agahigian chronicles the history and goals of optometry. He describes its differences with ophthamology and decries the cost and conflicts the lobbying activities of each group have caused. In order to better serve the public and to forestall a political solution by angry and exasperated legislators, he proposes that a study committee be formed to settle the differences. The agenda would begin with items he views as easy to compromise. The group would then progress to the drug bill and other legislation aimed at further extending the right of the optometrist to diagnose and treat eye disease.

His proposal, while laudable, is not credible. This joint conference committee approach has been tried in the past in Connecticut and has failed. It failed in times more conducive to negotiation than exist now. The present national policy of optometry, as noted in the article, calls not for parity but for replacement of the ophthamologist as the primary physician for eye care. Calling for revolution, not even evolution, this is untenable. No accommodation at the state level is possible under these circumstances.

Finally, the author hopes, that after reading his article, the profession will realize that this conflict is not unique; and that we will all be affected by these persistent efforts of non-medical practitioners to obtain the society's permission to increasingly diagnose and treat disease.

Of course! Will we never learn? The ophthamologists are still carrying on almost single handedly. When psychiatrists were attacked in the late 1960's we stood back thus giving the appearance of tacit approval. We did not support the obstetricians in the mid 1970's when they opposed exposing newborns to the needless risks inherent in the proposals of the non-professional birthing activists. Later in the same decade, even the House of Delegates of the AMA didn't seem to care much when radiologists and orthopedists argued against professional recognition of the chiropractic. We have yawned and looked the other way long enough. An attack against any segment of medicine is an attack against us all.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself responsible for statements made by any contributor.

Ultimately, despite the hopes of the author and whether we like it or not, these territorial disputes will be solved politically. This fact of life demands that we, as patient advocates, become more involved in the political process. This in turn calls for more lobbying and more frequent appearances at the Capitol. It also calls, not only for more of the proverbial one on one contact, but also for smaller county meetings with county legislators away from the Roman circus atmosphere of public hearings.

The greatest resource we have for maintaining quality care in the medical commons is an informed and concerned public—especially their legislators.

Guy W. Van Syckle, M.D.

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

FUTURE EXPECTATIONS—NUTRITIONAL

To the Editor: There is growing concern that the nutritional support offered to hospital patients, primarily the elderly patient, especially after hospital discharge, may be downgraded in the future. Presently it is not common for the hospitalized patient to be assigned a diagnosis of malnutrition, and very infrequently are the diagnosis of kwaschiokor, marasmus, or mixed kwaschiorkor marasmus placed on the final diagnosis sheet.

With the advent of the DRG System, it behooves all clinicians to properly code malunutrition when it exists in their hospitalized patient. However, within the 467 diagnostic related groups there are only three in a category which includes metabolic disorders other than inborn errors of metabolism. In the 296 category, this includes patients over age 70. The 297 category includes patients over age 18 but under age 70, while category 298 includes patients 0-17.

It is feared that hospitals in the DRG context will not be directly reimbursed for specialized nutritional support. With the estimate that DRG's will create a net effect of a decrease in hospital census nationwide, and an increase in a percent of more seriously ill patients, it is possible that the nutritional support presently expected of our hospitalized patients may suffer and be downgraded.

Already we note that it is difficult to discharge the stroke or neurological patient with a feeding gastrostomy or feeding jejunostomy. Nursing homes in Southern Connecticut are not by large receiving these patients for a variety of reasons, one being their inability to cover their costs and still derive a profit. We know that there are less and less R.N.'s working in nursing homes. Often there is one R.N. per 60 patients, and nurse aides are usually not qualified in giving enterostomy or gastrostomy feedings.

For the home bound patients, if there are family members, or luxuriously a full time nurse to aide these patients, enteral and gastric feedings can be provided. If a Home Health Care agency is needed to provide these services, costs can accelerate and without proper insurance coverage, these can be quite expensive.

DRG legislation means a trend in shorter hospital day stays, and probably shorter periods of intense nutritional support. This may be detrimental to many patients. As patients may be sent home, or to specialized nursing homes, in light of shortened hospital stay, it may be presumed that more and more of the elderly will be sent out with marginal or frank malnutrition. Whereas, we anticipate that the Home Health Care Agencies will be available to help us treat these patients, the cost involved is not inconsequential and as the insurance industry is not anxious to get involved, the cost may be largely borne by these individuals or their families.

The Connecticut Business and Industry Association is presently lobbying Connecticut legislators to vote in an all payor, prospective payment system, in which hospitals will be prepaid for all patients. Contrary to their belief that quality of care will not be compromised, it is so obvious that it would have to be compromised severely. We in the nutritional support aspect of patient care fear downgrading of services, especially in our area, as specialized nutritional support is so poorly compensated for at the present time, and is not considered seriously in the present DRG System.

I trust that this message be understood by our physicians, by our legislators, and companies as it deals with lives on a day to day basis. Now that we have been awakened to the importance of specialized nutritional support services, we should utilize them fully, not downgrade them.

Walter Pleban, M.D.

Chairman, Nutritional Support
Services—Bridgeport Hospital
Bridgeport, CT

VA Acute Care Seen Sufficient for Elderly Vets

The rapid graying of American veterans will probably lead to increased use of the free health care provided by the Veterans Administration (VA). But this increase may not be as much as expected even though the number of elderly veterans will nearly double by 1990, and veterans without service-connected disabilities become eligible for free VA medical care at age 65. According to a new study by the National Center for Health Services Research (NCHSR), many elderly veterans will probably take advantage of free VA prescriptions, short-term hospital inpatient care, and ambulatory physician services. However, the study suggests that the increase in use of VA acute care services will not be so large as to be overwhelming. For example, elderly veterans will represent a minority of VA patients, despite their increase in numbers. At the same time, the VA system will be providing less acute care to younger veterans whose numbers are steadily diminishing. More significant may be the finding that many elderly veterans now covered by private supplemental health insurance as well as by Medicare obtain care outside the VA system. This suggests that the demand for the VA acute care services may depend on whether elderly veterans have private health insurance in addition to Medicare. Those who do will be less likely to rely on the VA system. The study was done as part of the National Health Care Expenditures Study, a major NCHSR intramural research project analyzing policy-relevant data from the largest survey ever conducted of national health care costs and use. Findings appeared in the Fall 1983 issue of *Health Affairs* in an article by NCHSR researchers Constance Horgan and Amy Taylor, Ph.D., and Gail Wilensky, Ph.D., formerly of NCHSR. Copies of "Aging Veterans: Will They Overwhelm the VA Medical System?" are available from NCHSR.*

192nd ANNUAL MEETING
# of the
CONNECTICUT STATE MEDICAL SOCIETY
May 9, 10, 1984
Parkview Hilton Hotel
Hartford, Connecticut

COMMITTEE ON PROGRAM OF
SCIENTIFIC ASSEMBLY

Edward Dunn, M.D., Waterbury, Chairman
Ramon N. Kranwinkel, M.D., Danbury
Thomas J. Spackman, M.D., Farmington
Franklin Robinson, M.D., New Haven
Norman J. Marieb, M.D., New Haven

A MESSAGE FROM THE PRESIDENT

As President, I urge all members to participate in the 192nd Annual Meeting of the Connecticut State Medical Society. This is an opportunity for every member to participate in some part of the program.

With government intervention already a fact of life in certain segments of medical practice and with the threat of other legislation in process, which if enacted, will intrude in the delivery of medical care and the private practice of medicine, this year's meeting of the House of Delegates on Wednesday, May 9, should prove of special interest to all physicians.

The House of Delegates is an open meeting and all members of the Society are invited to attend. Not only can members observe their elected representatives in action, doing their best to deal effectively with the rapidly changing legislative, economic and social issues of the day in relation to the care of patients, but they will have a chance to express their own views at reference committee hearings, where most of the items coming before the House will be heard.

The inauguration of the new President, Joseph S. Sadowski, M.D., of Hartford, will take place at the House of Delegates meeting and will be followed by a reception for the President immediately following the close of the meeting.

A timely scientific program will be presented on Thursday, May 10. Two symposiums will be presented one on the therapy of coronary artery disease, and the other on critical ethical decisions and current medical treatment. This program should be of interest to all of us and it is also an excellent opportunity to obtain CME Category 1 credit on an hour for hour basis.

Many of us have failed to take advantage of the opportunity to become involved in this program by attending this meeting, however, I urge you to attend this year. There is something to be learned by everyone.

Daniel W. Doctor, M.D.

GENERAL INFORMATION
READ CAREFULLY

REGISTRATION

The registration desk will be located in the lobby of the hotel and everyone attending the meeting is requested to register. There will be no charge for registration and all members of the Society will be given a guest luncheon ticket when and only if they register.

PARKING

There are parking facilities at the hotel and in the immediate surrounding area.

TELEPHONE

Telephone messages will be received at Hartford 249-5611.

LUNCHEON

Luncheon will be served in the ballroom on the mezzanine floor and ALL MEMBERS OF THE SOCIETY REGISTERING WILL BE THE GUESTS OF THE SOCIETY. PLEASE REMEMBER A LUNCHEON TICKET WILL BE GIVEN TO MEMBERS ONLY IF THEY REGISTER.

HOTEL ACCOMMODATIONS

Persons who wish to stay overnight at the hotel should make room reservations as soon as possible. Please indicate in your letter that you are attending the Connecticut State Medical Society Meeting.

PROGRAM

The House of Delegates will be held on May 9th and the scientific program will be held on May 10th. The scientific program will be concentrated in one day, May 10th. The general program will be held in the ballroom between 10:30 A.M. and 4:00 P.M. and the section meetings will be held in the morning at 8:30 A.M. and in the afternoon at 4:00 P.M. in the rooms listed in the program.

PRESIDENT'S INAUGURATION

In a change of format, the inauguration of the new President will take place at the House of Delegates meeting on May 9th, at about 4:30 P.M. All members are invited to attend the inauguration. The annual dinner will be replaced with a reception following the close of the meeting.

EXHIBITS

All the exhibits will be located on the mezzanine floor. Physicians should take advantage of the opportunity to review what is new and timely by visiting the commercial exhibits.

ALL ACTIVITIES WILL TAKE PLACE AT THE HOTEL UNLESS OTHERWISE INDICATED

HOSPITAL RESIDENTS, INTERNS AND MEDICAL STUDENTS ARE CORDIALLY INVITED TO ATTEND THIS MEETING

ANNUAL MEETING OF THE HOUSE OF DELEGATES
WEDNESDAY, MAY 9, 1984

BALLROOM MEZZANINE

Presiding:

Lawrence B. Ahrens, M.D., Wethersfield, Speaker of the House
Joseph C. Czarsty, M.D., Oakville, Vice-Speaker of the House

12:00 REGISTRATION OF DELEGATES
Light sandwich buffet will be available

12:30 CALL TO ORDER

REPORTS OF OFFICERS, COMMITTEES, OTHERS

OLD AND NEW BUSINESS

GUEST SPEAKER: THOMAS R. BERGLUND, M.D., KALAMAZOO, MICHIGAN; SECRETARY, BOARD OF DIRECTORS, AMERICAN POLITICAL ACTION COMMITTEE

ADDRESS OF THE PRESIDENT—DANIEL W. DOCTOR, M.D., WESTPORT

ELECTION OF OFFICERS AND COMMITTEES

INTRODUCTION OF GUESTS

PRESENTATIONS AND AWARDS

INAUGURATION OF THE NEW PRESIDENT—JOSEPH S. SADOWSKI, M.D., HARTFORD

INAUGURAL ADDRESS

ADJOURNMENT

RECEPTION TO FOLLOW

GENERAL SCIENTIFIC PROGRAM
THURSDAY, MAY 10
MORNING SESSION

8:15 REGISTRATION—Hotel Lobby

8:30 -10:00 MEETINGS OF SECTIONS OF THE SOCIETY
(Listing elsewhere in program)

10:00 INTERMISSION TO VISIT EXHIBITS—Mezzanine

BALLROOM

10:20 CALL TO ORDER AND WELCOMING REMARKS
Joseph S. Sadowski, M.D., Hartford, President, Connecticut State Medical Society
Presiding: Norman J. Marieb, M.D., *New Haven*

SYMPOSIUM—THERAPY OF CORONARY ARTERY DISEASE

10:30 CALCIUM CHANNEL BLOCKERS
FRANCIS J. KLOCKE, M.D., Buffalo, New York; Chief, Division of Cardiology, State University of New York; Professor of Medicine and Physiology, State University of New York

11:00 CORONARY ANGIOPLASTY—INDICATIONS AND RESULTS
JOHN S. DOUGLAS, JR., M.D., Atlanta, Georgia: Associate Professor of Medicine (Cardiology); Assistant Professor of Radiology (Cardiac Radiology), Emory University School of Medicine

11:30 PROGRESS IN SURGICAL TREATMENT OF CORONARY ATHEROSCLEROSIS
FLOYD D. LOOP, M.D., Cleveland, Ohio; Chairman, Department of Thoracic and Cardiovascular Surgery, Cleveland Clinic Foundation

12:00 PANEL DISCUSSION
Francis J. Klocke, M.D., Buffalo, New York
John S. Douglas, Jr., M.D., Atlanta, Georgia
Floyd D. Loop, M.D., Cleveland, Ohio

12:30 INTERMISSION TO VISIT EXHIBITS

1:00 LUNCHEON—Ballroom—South

AFTERNOON SESSION

Presiding: Franklin Robinson, M.D., *New Haven*

SYMPOSIUM—CRITICAL ETHICAL DECISIONS AND CURRENT MEDICAL TREATMENT

2:00 ETHICAL AND LEGAL DIMENSIONS OF MEDICAL DECISION MAKING—THE SEARCH FOR CLARIFICATION
JOSEPH M. HEALEY, JR., J.D., Farmington, Connecticut; Associate Professor Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington

2:30 LEGAL ASPECTS OF DECISION MAKING FOR CRITICALLY ILL PATIENTS
ANGELA R. HOLDER, LL.M., New Haven, Connecticut; Clinical Professor of Pediatrics (Law), Yale University School of Medicine; Counsel for Medicolegal Affairs, Yale University School of Medicine and Yale-New Haven Hospital

3:00 THE PHYSICIAN AS ETHICIST
RICHARD T. NOLAN, Ph.D., Bristol, Connecticut; Professor of Philosophy and Social Sciences, Mattatuck Community College, Waterbury

3:30 PANEL DISCUSSION
Joseph M. Healey, Jr., J.D., Farmington, Connecticut
Angela R. Holder, LL.M., New Haven, Connecticut
Richard T. Nolan, Ph.D., Bristol, Connecticut

INTERMISSION TO VISIT EXHIBITS

4:00 MEETINGS OF SECTIONS OF THE SOCIETY
(Listing elsewhere in Program)

THURSDAY, MAY 10
MEETINGS OF SECTIONS OF THE SOCIETY
MORNING SECTION PROGRAMS

SECTION ON DERMATOLOGY

12:00 Noon Capital Ballroom

President: Stuart H. Bender, M.D., *Westport*
Secretary: Donald R. Greene, M.D., *Branford*

12:00 SOCIAL HOUR
1:00 LUNCH
2:00 BUSINESS MEETING—ELECTION OF OFFICERS
2:30 LECTURE
JOSEPH E. JELINEK, M.D., New York; Clinical Professor of Dermatology, New York University

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SECTION ON FAMILY PRACTICE

8:30 A.M. Colt Rooms A & B

President: Neil H. Brooks, M.D., *Rockville*
Secretary: Stephen T. O'Brien, M.D., *Enfield*

BUSINESS MEETING
ELECTION OF OFFICERS
GUEST SPEAKER: RONALD PINKERTON, M.D., Middletown: Assistant Director, Middlesex Memorial Hospital Family Practice Residency Program

Topic—Family Practice Research—Results of a Statewide Urinary Tract Infection Project

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SECTION ON PEDIATRICS

8:30 A.M. Goodwin Room

President: E. Maurice Wakeman, M.D., *Guilford*
Secretary: Katherine Prioli, M.D., *Norwich*

THE SILENT EPIDEMIC—CHILDHOOD ACCIDENTS
LEONARD S. KRASSNER, M.D., New Haven; Chairman, Accident Prevention Committee of American Academy of Pediatrics

SECTION ON PHYSICAL MEDICINE AND REHABILITATION

8:30 A.M. Bushnell Room

President: Philip B. Arnold, M.D., *Danbury*
Secretary: Francis X. Palermo, M.D., *Wallingford*

MARKETING REHABILITATION TO THE PUBLIC
CHARLES R. MARSHALL, M.D., Stamford; Director of Physical Medicine and Rehabilitation, St. Joseph's Hospital

SECTION ON PSYCHIATRY

8:30 A.M. Colt Room C

President: Howard V. Zonana, M.D., *New Haven*
Secretary: Theodore Zanker, M.D., *New Haven*

BUSINESS MEETING

ELECTION OF OFFICERS

GUEST SPEAKER

AFTERNOON SECTION PROGRAMS

SECTION ON ALLERGY

4:00 P.M. Colt Room C

President: Robert L. DeBernardo, M.D., *Bridgeport*
Secretary: Gerald J. Germano, M.D., *Ansonia*

4:00 BUSINESS MEETING
ELECTION OF OFFICERS

7:00 Dinner—Colt Room B & C
Guest Speaker

SECTION ON ANESTHESIA

4:00 P.M.

President: James C. Rouman, M.D., *Hartford*
Secretary: Gerald G. Piserchia, M.D., *Hartford*

4:00 EXECUTIVE COMMITTEE—Charter Oak Room

5:00 BUSINESS MEETING—Bushnell Room

6:00 GUEST SPEAKER
DENNIS W. COOMBS, M.D., Hanover, New Hampshire; Professor Anesthesiology, Dartmouth-Hitchcock Medical Center
Topic—Prophylaxis for Acid Aspiration

7:00 DINNER—Elizabeth Room

SECTION ON NEUROSURGERY

4:00 P.M. Colt Room A

President: Norman H. Gahm, M.D., *Hartford*
Secretary: John N. German, M.D., *New London*

PEDIATRIC HEAD INJURIES
CHARLES C. DUNCAN, M.D., New Haven; Associate Professor of Surgery (Neurosurgery and Pediatrics) Yale University School of Medicine

SECTION ON OBSTETRICS AND GYNECOLOGY

4:00 P.M. Executive B, Fourth Floor

President: John M. Gibbons, M.D., *Hartford*
Secretary: Edwin J.T. Moore, M.D., *Waterbury*

MENOPAUSAL ESTROGEN THERAPY AND ENDOMETRIAL CANCER
JAMES S. HOFFMAN, M.D., Farmington; Associate Professor of Obstetrics and Gynecology and Director of Gynecologic Oncology, University of Connecticut School of Medicine

SECTION ON ORTHOPEDICS

3:00 P.M. Hunt Memorial Building
230 Scarborough St., Hartford

President: Thomas M. Malloy, M.D., *Danbury*
Secretary: John D. Haugh, M.D., *Hartford*

ANTERIOR CRUCIATE REPAIRS
W. NORMAN SCOTT, M.D., New York; Chief of Implant Surgery, Lenox Hill Hospital; Team Physician for New York Rangers and New York Knickerbockers

CONSERVATIVE TREATMENT OF CRUCIATE INJURY
PETER JOKL, M.D., New Haven; Team Physician, Yale University; Associal Clinical Professor of Orthopedics, Yale University School of Medicine; Director, Sports Medicine Center, Hospital of St. Raphael

SECTION ON PATHOLOGY

4:00 P.M. Room 424

President: William T. Pastuszak, M.D., *Hartford*
Secretary: Dante B. Cannarozzi, M.D., *Waterbury*

PATHOLOGY REIMBURSEMENT AND SEPARATE BILLING
MR. ROBERT TESSIER, Fort Lee, New Jersey; Reimbursement Consultant, HBP Services, Inc.

SECTION ON SURGERY

4:00 P.M. Colt Room B

President: Allan L. Toole, M.D., *New Haven*
Secretary: Martin Dinep, M.D., *New Britain*

BUSINESS MEETING

ELECTION OF OFFICERS

SECTION ON THORACIC SURGERY

4:30 P.M. Goodwin Room

President: Joseph P. Dineen, M.D., *Ansonia*
Secretary: Allan L. Toole, M.D., *New Haven*

BUSINESS MEETING

ELECTION OF OFFICERS

SECTION ON UROLOGY

4:00 P.M. Pope Room

President: James F. Walsh, III, M.D., *Bridgeport*
Secretary: Haik Kavookjian, Jr., M.D, *Stamford*

BUSINESS MEETING

ELECTION OF OFFICERS

POSTGRADUATE PHYSICIAN SECTION

4:00 P.M. Ballroom

FIRST CONNECTICUT RESIDENTS SYMPOSIUM ON CANCER

Sponsored by: Connecticut Chapter: American College of Surgeons
Connecticut Society of American Board Surgeons, Inc.

Presiding: Robert E. Sax, M.D., *Bridgeport*

4:00 PRESENTATION OF WINNING PAPERS WRITTEN BY RESIDENTS ON TOPICS RELATING TO THE MULTI-DISCIPLINE APPROACH TO CANCER

6:00 RECEPTION—Bushnell Room-Foyer

7:00 DINNER—Bushnell Room
Guest Speaker: RICHARD E. WILSON, M.D., Boston; Professor of Surgery, Harvard Medical School; Chief, Surgical Oncology, Brigham and Women's Hospital and Sidney Farber Cancer Institute

Presentations of Awards for Prize Winning Papers

(This program also supported by the Connecticut Chapter of the American Cancer Society and the Cancer Coordinating Committee of the Connecticut State Medical Society.)

SPECIAL NOTICES
CONTINUING MEDICAL EDUCATION CREDITS

AMA PHYSICIAN'S RECOGNITION AWARD

As an organization accredited for continuing medical education by the Affiliation Committee for Continuing Medical Education, Yale University School of Medicine certifies that this program is acceptable for Category 1 credit as specified by the American Medical Association for the Physicians Recognition Award. Credit is granted in this category on an hour for hour basis.

AMERICAN ACADEMY OF FAMILY PHYSICIANS

The Commission on Education of the AAFP has accredited the scientific program of the Society's Annual Meeting for five and one half hours of prescribed credit for the general lectures and the family practice section meeting, and one and one half hours of elective credit for each lecture attended which is presented by the individual specialty sections of the Society.

THE CONNECTICUT STATE MEDICAL SOCIETY acknowledges with thanks a program grant received from Eli Lilly and Company, Indianapolis, Indiana.

Our exhibits contribute to the value of our assembly by presenting goods and services of interest and importance to physicians. Personal visits to the booths will increase your understanding of the materials and programs on display.

TECHNICAL EXHIBITS

Applied Management Systems, Inc., New Haven, Connecticut
Ayr Insurance Agency, Inc., New Haven, Connecticut
Boots Pharmaceutical, Inc., Shreveport, Louisiana
Connecticut Army National Guard
Data Systems of Connecticut, Milford, Connecticut
Geigy Pharmaceuticals, Summit, New Jersey
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U. S. Army Medical Department
U. S. Naval Recruiting Service
Walleby Software Company, Ramsey, New Jersey
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in Brief

A summary of AMA, medical & health news

The AMA is working with state and national specialty societies to promote the goals of a one-year voluntary freeze on physician fees. The Board of Trustees action calling for the freeze was announced at the AMA National Leadership Conference late in February. A letter from the Association to approximately 390,000 physicians asks physicians to freeze their fees for one year, to continue taking into account the financial circumstances of patients — especially the unemployed, the uninsured, and those on Medicare — and to accept reduced fees when warranted. Board of Trustees Chairman John J. Coury Jr., MD, said he estimated that 85 to 90% of the nation's physicians would participate.

A peer-to-peer membership recruitment program will be implemented by the AMA in the 1984 membership year. State and specialty delegations will be provided with lists of physicians who belong to their society but not to the AMA. Unified states will receive lists of nonmembers at all levels. From these lists, delegates and alternate delegates will select five nonmembers in their communities to recruit for AMA membership. To facilitate the selection of specialty society members who do not belong to the AMA, specialty society delegates will be asked to provide their society's membership roster to the AMA before the AMA Annual Meeting. The AMA will provide delegates and alternates with background information on prospective members as well as appropriate peer-to-peer material. A report on the program will be made at the AMA Interim Meeting in December. Awards will be presented to top recruiters and the top delegation.

Five state medical societies have formed hospital medical staff sections, according to preliminary results of an AMA survey. They are Arizona, California, Idaho, Maine, and Minnesota. Ten other states are in the process of forming sections: Colorado, Connecticut, Michigan, Oklahoma, Pennsylvania, South Carolina, Texas, Utah, Virginia, and Washington. States that said they have not formed sections but have other programs in place are Illinois, Iowa, Kansas, Mississippi, North Dakota, and Vermont.

Ohio and Texas increased their 1984 AMA delegate counts by one each. No states lost seats in the new allocation. As a result, 353 delegates will be credentialed this year for the Annual and Interim Meetings of the House.

An Ad Hoc Committee on Foreign Medical Graduates was established by the AMA Board of Trustees to study the problems and special concerns of FMGs, including U.S. citizens who studied medicine abroad. The study will focus on current issues in residency training, examinations, licensure, immigration policies, and employment opportunities. The ten-member committee will serve for two years and is expected to increase the involvement of FMGs in organized medicine.

AMA Audio Medical News announced discounts for one-year and for seven-month subscriptions to audiocassette digests of socioeconomic medical news. Each issue provides a one-hour presentation of news, commentary, and interviews on such topics as the effects of increased competition, changes in reimbursement and delivery, and health planning. A 30% discount reduces the cost of a $96 yearly subscription to $67. A 20% discount reduces the cost of a seven-month trial subscription from $56 to $44. For more information, call 1-800-621-8325. In Illinois call collect at 312-645-5061.

Physician inquiries to the AMA library increased 82% last year, rising from 8,147 at the end of 1982 to 14,850 in 1983. Total inquiries — including those from physicians, AMA and Federation staff, the public, and hospitals — rose from 48,426 in 1982 to 54,001. Last year, 1,215 of the total inquiries were for information on AMA policy positions, statements, publications, and reports.

The AMA's Physicians' Placement Service is now offering free registration to members. PPS is a computerized information clearinghouse that provides listings of practice opportunities in nearly every medical specialty. Two bimonthly registers are published: the "Opportunity Placement Register," which contains short descriptions of available practice opportunities, and the "Physician Placement Register," which contains abbreviated curricula vitae. During 1983, PPS-registered physicians requested more than 8,900 practice listings from the OPR. Employers requested more than 18,600 curricula vitae from the PPR. For more information, call 312-645-4712.

The AMA submitted 62 statements to Congress on pending legislation and 46 statements to administrative agencies on pending regulatory matters during 1983.

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MANUSCRIPTS should be submitted to the Editor, J. Alfred Fabro, M.D., *Connecticut Medicine*, 160 St. Ronan St., New Haven, CT. 06511. Manuscripts are received with the explicit understanding that they are not simultaneously under consideration by any other publication.

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PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

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Internist wanted as full-time Staff Physician for 500-bed multi-licensed, JCAH approved geriatric institution. Geriatric experience preferred. Will work standard workweek, rotation of evening and weekend call. Please send resume with salary requirement to: Director of Personnel, Masonic Home and Hospital, P.O. Box 70, Wallingford, CT 06492.

INSTITUTIONAL MEDICINE—Continued

BC/BE primary care physicians needed to join new immediate medical care facility in East Hartford. Please reply with C.V. and date of availability to CSMS. INST/MTG.

Walk-In Medical Services is seeking full and part-time physicians to work in a convenience medical facility in Orange, CT. Family Practice/Internal Medicine preferred. Reply to CSMS, INST/RBH.

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OPHTHALMOLOGY

July '84. Age 29. Nat'l bds. AB cert. (Pediatrics). AB elig. (Ophthal). MD, Chicago Medical School; Int., North Shore University Hospital (Pediatrics); Res., North Shore University Hospital (Pediatrics) and State University of NY, Downstate Medical Center (Ophthal). Prefers group or associate type practice. Although trained in all aspects of ophthalmology would like to practice general ophthalmology with an emphasis on pediatric eye diseases. Write, Andrew E. Gewirtz, M.D., 519 Beach 133 St., Belle Harbor, NY 11694.

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PHYSICIANS WISHING TO PRACTICE IN CONNECTICUT

ANESTHESIOLOGY

Sept. '84. Age 32. AB elig. MD and Int., Calicut Medical College, India; Res., University René Descartes, Paris, France and Allegheny General Hospital, Pittsburgh, PA. Prefers to be in a hospital of at least 250 beds and/or group practice. Write, Jayam Krishna Iyer, M.D., 436 TA, Chatham Park Dr., Pittsburgh, PA 15220.

Aug. '84. Age 30. Presently in practice. FLEX. AB elig. MD, Baroda Medical College, India; Int., Bronx Lebanon Hospital, Bronx, NY; Res., Mount Sinai Medical School and Long Island Jewish-Hillside Medical Center, NY. Prefers group, assoc. or institutional type practice in a small to medium-sized community. Write, R.S. Saraiya, M.D., 88-25A, 153rd St., #4F, Jamaica, NY 11432.

INSTITUTIONAL/INDUSTRIAL MEDICINE

OCCUPATIONAL. April '84. Age 69. Licensed in Connecticut. Nat'l bds. AB cert. MD, Cornell; Int., two years rotating; USAF-MC, four years. Available ft/pt staff, Hartford area. Write, Lamson Blaney, M.D., Box 154, Mansfield Center, CT 06250.

June '84. Age 59. Licensed in Connecticut. Presently in practice. Nat'l bds. AB cert. MD, Georgetown University; Int., Georgetown Hospital, Washington, DC; Res., B.U. University Hospital, Boston City Hospital. Desires position in Occupational Medicine. Nine years experience in Emergency Medicine. Eight years experience in Occupational Medicine. For futher information contact, Louis Z. Fauteux, Jr., M.D., 141 Weston St., Hartford, CT 06101.

INTERNAL MEDICINE

July '84. Age 32. Nat'l bds. AB elig. MD, Autonomous University of Guadalajara, Mexico; Int. and Res., Prince George's General Hospital, Cheverly, MD. Prefers solo, group or associate type practice. Write, James E. Sullivan, M.D., 5009 Cheyeenne Place, College Park, MD 20740.

May '84. Age 32. Licensed in Connecticut. AB elig. MD, Louisiana State University; Int. and Res., Danbury Hospital. Currently working in Emergency Room Service. Prefers group or associate type practice in a medium to large-sized community. Write, Phil Watsky, M.D., 101 Wilbourne #904, Lafayette, LA 70506.

July '84. Age 35. FLEX. AB elig. MD, St. George's University School of Medicine; Int. and Res., Memorial Hospital (Brown University Association). Prefers solo or associate type practice in a small to medium-sized community. Write, Brian Hennessy, M.D., 5 Chestnut St., Pawtucket, RI 02860.

April '84. Age 29. Nat'l bds. AB elig. MD, SUNY at Buffalo, NY; Int. and Res., Albany Medical College, NY. Prefers solo, group or associate type practice in a small to medium-sized community. Write, Nicholas Bertini, M.D., 663 Hudson Ave., Albany, NY 12203.

Summer '84. Age 30. Nat'l bds. AB elig. MD, Emory University School of Medicine; Int. and Res., University of Virginia Hospital. Wishes to join an established group practice or clinic with both outpatient and inpatient care although an outpatient setting alone could be acceptable. Write, CSMS, CLS/IM.

July '84. Age 28. Nat'd bds. AB elig. MD and Int., Wayne State University, Detroit, MI; Res., St. Joseph Mercy Hospital, Ann Arbor, MI (University of Michigan affiliate). Prefers group or institutional type practice in a large-sized community preferably Hartford or New Haven. Write, Victoria D. Woods, M.D., 2124 Pauline Blvd., #208, Ann Arbor, MI 48103.

CARDIOLOGY. July '84. Age 31. MD, Government Medical College, Punjabi University, Patiala, Punjab, India; Int., Rajindra Hospital, Patiala, India; Res., Mt. Carmel Mercy Hospital, Detroit, MI; Fellowship, St. Vincent Hospital, Worcester, MA. Will look into any good opportunity and type of practice. Write, Navtej Singh Rangi, M.D., 21 Heywood St., #HC, Worcester, MA 01604.

ENDOCRINOLOGY. July '84. Age 38. Licensed in Connecticut. FLEX. AB elig. MD, Faculty of Medicine, Cairo University; Res., Mercy Hospital, Buffalo, NY; Fellowship, University of California Irvine and St. Francis Hospital and Medical Center, Hartford, CT. Desires solo, group or associate type practice in a medium to large-sized community. Write Tarek L. Haw, M.D., 1921 Asylum Avenue, Apt. 420, Hartford, CT 06105.

GASTROENTEROLOGY. Immediately available. Age 38. AB cert. MD, Karnatak Medical College, India; Int., St. John Hospital, Cleveland, OH; Res. and Fellowship, Jewish Hospital & Medical Center of Brooklyn. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Prakash V. Huded, M.D., 80-15, 41st Ave. #606, Elmhurst, NY 11373.

GASTROENTEROLOGY. Age 32. FLEX. AB elig. MD Stanley Medical College, Madras, India; Int. and Res., VA Hospital, Bronx, NY; Fellowship, Middlesex General University Hospital, Rutgers Medical School, New Brunswick, NJ. Prefers solo or associate type practice. Write, Palaniswamy Kothandaraman, M.D., 9 Lake Avenue, Apt. 5A, East Brunswick, NJ 08816.

GASTROENTEROLOGY. July '84. Age 34. FLEX. AB elig. MD, Universidad Autonoma de Guadalajara, Mexico; Int. and Res., St. Barnabas Medical Center, Livingston, NJ; Fellowship, University of Pittsburgh, PA. Skilled in all endoscopic procedures. Prefers group or associate type practice. Write, CSMS, SL/IM.

HEMATOLOGY/ONCOLOGY. July '84. Age 31. Nat'l bds. AB cert. MD, Downstate Medical Center of State University of NY; Int., Metropolitan Hospital/NY Medical College; Res., Metropolitan Hospital/NY Medical College/Harlem Hospital; Fellowship, NY University Medical Center (Hematology/Oncology). Prefers solo, group, associate or institutional type practice. Write, Lynn J. Morris, M.D., 231 East 76th St., New York, NY 10021.

PULMONARY DISEASE. July '84. Age 31. AB elig. MD, B.J. Medical College, India; Int., B.J. Medical College affiliated hospitals; Res., Helene Fuld Medical Center, Trenton, NJ; Fellowship, Brookdale Hospital Medical Center, Brooklyn, NY. Desires solo, group, associate or institutional type practice. Write, Dinesh C. Talati, M.D., 66-02 Grand Central Parkway, Apt. 1-B, Forest Hills, NY 11375.

Treatment of Chylous Ascites by Side-to-Side Portacaval Shunt

ABSTRACT—Persistent portal hypertension plus operative injury to intestinal lymphatics may result in intractable chylous ascites. An instance where central portal venous decompression was followed by immediate and prolonged relief of chylous ascites in a patient with alcoholic cirrhosis has been described.

Introduction

Chylous ascites in patients with cirrhosis is a rare phenomenon. It has been described in unoperated patients [1-4] and after selective venous shunting by Maywood et al.[5] No standard therapy has been established, and most authors have recommended a conservative approach. However, the condition may be progressive and disabling. A recent experience has demonstrated that there may occasionally be a place for operative correction of this unusual condition.

Case Report

Eighteen months prior to admission, a 38-year-old white male patient underwent distal splenorenal (Warren-Zeppa) shunt after a third episode of bleeding from esophageal varices secondary to alcoholic cirrhosis. Recurrent bleeding nine months later led to the demonstration of a thrombosed shunt and construction of a mesocaval Gore-tex interposition shunt. Prompt recurrence of hemorrhage post-operatively was managed by revision of the graft, but early re-thrombosis occurred. This was not treated because hemorrhage had ceased, and the patient was allowed to recover. Progressive ascites developed over the next six months in spite of intensive medical therapy and was accompanied by profound muscle wasting and weakness.

On hospital admission, the patient was alert and cooperative, but demonstrated generalized muscle wasting and tense ascites. Laboratory data included a serum bilirubin of 1.5 mgm. percent and a serum albumin of 3.4 gm. percent. After seven days of salt restriction and therapy with multiple diuretics, the ascites remained unchanged. Diagnostic paracentesis yielded milky fluid with a triglyceride content of 2180 mgm/dl. Wedged hepatic venous pressure was 34 cm. of water and contrast injection demonstrated hepatofugal flow in the portal vein with large esophageal varices and no evidence of a patent surgical shunt.

After two weeks in the hospital, a side-to-side portacaval shunt was constructed. At this operation, five liters of chylous ascites were evacuated from the peritoneal cavity. The source of this fluid seemed to be at the root of the mesentery in direct proximity to the thrombosed Gore-tex prosthesis, but no attempt to control this leak was made. Post-operatively, the patient made an uneventful recovery with no evidence of reaccumulation of ascites or gastrointestinal hemorrhage. He was discharged on the 11th post-operative day and rapidly regained his muscle mass. He remains entirely well 14 months later without evidence of ascites or malnutrition.

Discussion

Cirrhotic patients with refractory ascites, whether before of after venous shunting operation, may occasionally have chylous ascites. Diagnostic paracentesis should be part of the evaluation of every such patient, and the discovery of chylous ascites may alter subsequent management.

Chylous ascites has been described after selective (Warren-Zeppa) venous shunting.[4] In that circumstance, portal venous and mesenteric lymphatic pressures may have been increased by selective venous decompression, and the lymphatics may have been injured during the dissection required by the operation. In our patient, there was a combination of persistent portal hypertension plus presumed operative trauma to the intestinal lymphatics at the root of the small bowel mesentery. The persistence of this disabling anatomic and metabolic derangement was not improved in spite of six months of conservative management.

Laparotomy may not reveal a discrete source of the chylous leak, and direct suture of visible lymphatic openings may be unsuccessful.[1,6] Placement of LeVeen or Denver shunts has been tried in patients with chylous ascites, but occlusion of the catheter has been a problem.[1,6] We could find no report of the treatment of chylous ascites by central venous shunting in patients with portal hypertension. However, the experimental work of Dumont et al demonstrated that thoracic duct lymph pressure was markedly increased in cirrhotic patients and that portal pressure could be reduced by

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GEORGE ECONOMOPOULOUS, M.D., Chief Resident, Department of Surgery, New Britain General Hospital, New Britain, CT. JAMES H. FOSTER, M.D., Professor and Chairman, Department of Surgery, University of Connecticut Health Center, Farmington, CT.

reducing thoracic duct pressure.[7] Would reduction of portal pressure reduce lymphatic pressure sufficient to correct chylous ascites? It seemed that decompression of the portal vein might theoretically accomplish two purposes in our patient: 1) the protection from recurrent hemorrhage from persistent esophageal varices; and 2) relief of lymphatic hypertension. The immediate and prolonged gratifying results following this operation in our patient suggests that this approach may have merit in selected cases.

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5. Maywood BT, Goldstein L, Busuttil RW: Chylous ascites after a Warren shunt. Am J Surg 135:700, 1978.
6. Press OW, Press NO, Kaufman S: Evaluation and management of chylous ascites. Ann Int Med 96:358, 1982.
7. Dumont AE, Mulholand JH: Alterations in thoracic duct lymph flow in hepatic cirrhosis. Ann Surg 156:668, 1962.

Management of Pediatric Head Injury

CHARLES C. DUNCAN, M.D. AND LAURA R. MENT, M.D.

Introduction

The most important aspect of the care of a head injured child is appropriate observation. Without question computerized axial tomography (CT scan) has significantly improved the care we are able to give such patients as well as have advanced monitoring and ventilatory support.[1-3] The appropriate utilization of these tools depends upon the observations made about the patient. Such observations began at the time of injury from witnesses, family and emergency medical personnel and extend to hospital arrival and intensive care observations. Indeed, such observations continue well past their acute phases, as the effects of head injury extend for many months to a lifetime even in situations of mild and moderate head injury.[4-7] Treatment for head injury is directed toward lessening the effect of the primary injury and preventing secondary brain injury.[8] Over half of the population in the U.S. who sustain severe head injury are between the ages of 19 and 24, which falls just above the pediatric age group in most centers.[9] However, trauma in the child is the leading cause of death in the pediatric age groups.[10] In many respects treatment for head injury is similar regardless of age about which a number of excellent articles and texts have been written,[11,12] however, the young present a set of particular problems when injured that follow the usual age groupings of pediatrics of the newborn and infant, toddler and younger child, older child and adolescent.[13,14] Inattention to the particular aspects of head injury within these groups is likely to prevent appropriate care which would minimize the effects of the primary, injury and avoid secondary brain injury.

Assessment

Assessment of the head injured patient begins at the time of injury. Observations made by witnesses and emergency personnel as to the mechanism of injury and the condition of the patient, particularly the level of consciousness, are extraordinarily important in the formulation of the injury for approaching the patient. The child who may slip on a slippery floor and strike his head is at a very different risk from the one with a high acceleration, deceleration injury from collision of bicycle and automobile even if both are awake and alert upon arrival to hospital.[15] As a consequence, training of emergency

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medical personnel and the primary health care individuals to the principles of head injury management would be expected to improve outcome as indicated from current studies well organized emergency medical care center statistics.[16] While these initial levels of care do not include the sophisticated fixed monitoring and diagnostic instrumentation of an intensive care unit and associated facilities, the people, the individual care givers at these early phases must exercise appropriate decision making from appropriate observations. The education of these individuals, who are not likely to be experts in pediatric head injury or intensive care, to the basic principles of care is likely to outweigh considerable technology utilized hours to days later.

Level of consciousness is far and away the most important parameter to observe and it must be observed over and over and over again in the course following injury.[11] In the past highly subjective assessments of level of consciousness were given which ranged from sleepy, lethargic, obtunded to comatose. Such evaluations meant little from observer to observer. Teasdale and Jennette in 1974[17] devised the Glasgow Coma Scale which while an imperfect tool permitted level of consciousness to be objectively determined with good interobserver reliability and was based on the parameters of eye opening, verbal response,and motor response as seen in Table 1 with mild head injury being defined as GCS of 15-13, moderate as 12-9 and severe as 8-3.[6,7] Similarly a scale for neonates had been devised for the young between 26 and 52 weeks post conceptual age based on response to light, bell and motor response as seen in Table 2.[18] Clearly, however, the older infant and young toddler remain difficult to objectively describe in terms of level of consciousness although each scale may to some extent be extended to older and younger individuals. Active investigations continue at the present time for more precise measurements of level of consciousness at a number of centers and in collaborative multicenter studies.[19]

Table 1
GLASGOW COMA SCALE

EYE OPENING	
Spontaneous	E4
To speech	3
To pain	2
nil	1
BEST MOTOR RESPONSE	
obeys	M6
localizes	5
withdraws	4
abnormal flexion	3
extensor response	2
nil	1
VERBAL RESPONSE	
orientated	V5
confused conversation	4
inappropriate words	3
incomprehensible sounds	2
nil	1
Coma score (E + M + V) = 3 to 15	

From Teasdale G, Jennett B: Assessment of coma and impaired consciousness, Lancet 2:81-84, 1974.

Table 2
NEONATAL AROUSAL SCALE

BEST RESPONSE TO BELL	
Facial and extremity movements	5
Grimaces/blinks	4
Increase in RR/HR	3
Seizures/extensor posturing	2
No response	1
BEST RESPONSE TO LIGHT	
Blink and facial/extremity movements	4
Blink	3
Seizures/extensor posturing	2
No response	1
BEST MOTOR RESPONSE	
Spontaneous	
Periods of activity alternating with sleep	6
Occasional spontaneous movements	5
Sternal Rub	
Extremity movements	4
Grimace/facial movements	3
Seizures/extensor posturing	2
No response	1
TOTAL	3-15

From Duncan CC, Ment LR, Smith B, Ehrenkranz RA: A scale for the assessment of neonatal neurological status. Child's Brain, 8:299-306, 1981.

Assessment of level of consciousness while foremost in the evaluation of head injury does not at all replace or lessen the importance of neurologic and general physical evaluation. Similarly, such evaluation must be repetitive and documented sufficiently well and objectively to permit continuity of care.[20]

Diagnostic Studies

The diagnostic studies used in the evaluations of head injury are primarily plane films and CT scan.[21,22] The role of each in management is at times controversial in terms of cost and expected benefit. Certainly, acute invasive procedures such as cerebral anteriography and exploratory burr holes are required at only selected special circumstances with the availability of CT scan. Skull x-rays are often forgotten with the availability of the CT scan and along with them the cervical spine. However, anyone who has sustained a head injury sufficient to render him unconscious has probably sustained sufficient force to the neck to break it so the cervical spine must be evaluated carefully regardless of the decisions made about other studies. Even with the CT scan the skull films are expected to better visualize skull fractures. As far as who should have CT scan following head injury, considerable opinion and controversy exists. At our institution any child arriving at hospital with an altered level of consciousness or a focal neurologic examination or acutely requires other operation with general anesthesia after even a brief loss of consciousness ordinarily undergoes CT scan. Depending upon the specific circumstances of the injury other diagnostic studies may be required such as angiography, myelography, laminography or ultrasound examination.

Initial Management

Initial management follows the basic guideline of elementary first aid.[23] The airway must be maintained with additional care given to the potential for cervical instability and the high likelihood of aspiration in the patient with altered level of consciousness. Hypovolemic shock is widely stated not to be the result of head injury and other sources of bleeding must be sought. The very young are the dramatic exception to this rule, for an infant may become hypovolemic from intracranial or even subgaleal hemorrhage.[10]

The usual signs of injury to the spine, chest, abdomen, or extremities in terms of guarding or splinting are not present in the unconscious patient. As a consequence peritoneal taps and survey films must be taken with a much lower threshold of suspicion than in an alert patient.[8]

Obviously, patients in coma or with a persistently altered level of consciousness will be admitted to hospital and treated in the intensive care situation, but how are children with a brief loss of consciousness managed and if they are admitted, for how long? Specific answers depend upon the customs and available facilities at individual institutions. The goal of such decisions is the prevention of secondary injury occurring with late bleeding and cerebral hyperemia or flash edema or infection from CSF leak.

Basilar skull fractures and maxillo facial injuries require two special precautions. The first is with care regarding placement of nasogastric tubes in order to avoid the complications seen in Figure 1. If such a tube is necessary it may be placed by hand or with direct oral visualization. With CSF leak from basilar skull fractures positive pressure ventilation by mask is likely to contaminate the basilar cisterns and lead to meningitis.

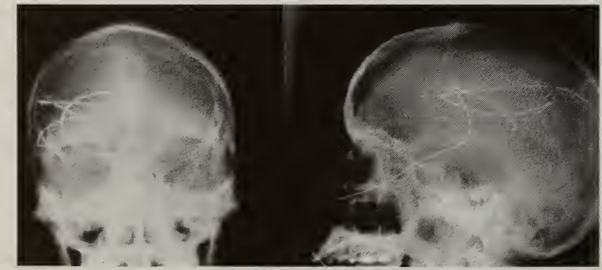

Figure 1

Initial management may blend very rapidly into a definitive operative management depending upon the nature of the injury. The timeliness of such intervention will in many instances provide the difference between recovery and death. Such urgency may take place upon arrival to hospital or later as the patient is undergoing observation.

Management Without Mass Lesion

Medical and surgical management of head injury are certainly not separate or sequential entities in the care of head injured patients. They must be conjoined or the patient is likely to lose the potential benefits of both. Appropriately organized observation of level of consciousness, neurologic examination, vital signs, laboratory values and use of like data is the central portion of management. Such aspects as the use of anticonvulsants, steroids, sedation, antibiotics, diuretic, fluid restriction and agents for cerebral protection depend upon the critical and experienced evaluation of this patient data.

Patients in coma for greater than six hours have an incidence of seizure approaching 50%. The routine use of anticonvulsants in this and less severe head injuries remains controversial. If anticonvulsants are used, they are not expected to be effective unless formal loading is carried out with appropriate maintenance dosage. Phenobarbitol is likely to confound assessment of level of consciousness, as a consequence dilantin is usually the drug of choice.[24] Steroids have not been definitively evaluated in head injury in a controlled fashion to show whether administration is beneficial. Pathological studies on pilot basis have indicated both response and lack of response.[25-27] Stress, including stress induced gastrointestinal bleeding, is a significant problem regardless of the decision about steroids and antacids and/or Hl blockage, should be given in moderate to severe head injuries.

Essentially all patients with an altered level of consciousness have an excessive output of ADA and need for a period of time a limited fluid intake. Measurement of electrolytes and osmolalities are essential for critical management of these parameters.[28]

Mass Lesions

The management of patients with significant mass lesions ordinarily requires operation.[30] Aggressive control of ICP is not likely to be of benefit with the entire volume taken up by the mass which is usually hemorrhage in the case of trauma. As well the structural shifts and distortion of brain are likely to cause irreversible damage. This text is not appropriate for the detailed discussion of operative techniques; however, the timeliness of such intervention cannot be over emphasized. Prior to the advent of CT scan, subdural hematomas followed by epidural hematomas were considered to be the most common intracranial mass lesion after head injury. CT scan has shown intracerebral hematomas to be the most frequent.[2] The presence of any mass lesion is not the indication in operation. Rather, the basic concepts of the patient's level of consciousness and neurologic examination are the determining factors. Following operations, miraculous cure is certainly not the rule although occasional patients, particularly those with epidural hematoma, may recover quite quickly.[31] More likely is a gradual and often protracted improvement if irreversible damage did not occur, as the cerebral edema resolves brain shifts improve and a number of very poorly understood events take place such as shifting dominance from left to right hemispheres in younger children.[32]

Unfortunately, operations for mass lesion once performed does not mean that, as the patient, continues repetitive evaluation in the intensive care unit that rebleeding in the same or a separate location may not occur. Equal vigilance must continue.

Subdural hematomas in the very young present a special opportunity for rapid early treatment with subdural taps. Even acute subdurals in this age group are likely to be lower attenuation of the CT scan than blood for the mixture that most often occurs with CSF. Short, shortly beveled subdural tap needles with trochars following appropriate prep with hair shaving may be carried out almost anywhere with immediate reduction in ICP. Both sides should be tapped in order to avoid brain shifts' as most such subdurals are bilateral. Certain caution must be exercised in the too rapid removal of subdural fluid similarly for fear of too rapid shift of brain. Taps are ordinarily carried out for a number of days. In over half of such cases subdural to peritoneal shunts are temporarily required to prevent the continued accumulation of fluid.[33,34]

Child Abuse

As discussed in the outset the mechanism of injury is an important aspect to management. Unless a very clearly understood traumatic event is known to have taken place, abuse must be suspected and appropriately investigated in order to prevent reinjury for abuse is not likely to be a single event but an ongoing pattern with a significant morbidity and mortality rate. Management should include discussion with family, skeletal survey, involvement of social services and reporting to state agencies as appropriate.[35,36]

Sequelae of Head Injury in Children

Appropriate to the discussion of head injury management is outcome, for the parent and the child as well must know what to expect. The westerns, spy books, and television programs depicting the traumatic loss of consciousness as a trivial transient event are wrong. Essentially everyone with a traumatic loss of consciousness has significant sequelae. Seizure threshold is likely to have been lowered. Headaches are likely to persist for weeks to months. Smell and taste are frequently disturbed. An intellectual function is all but the most transient events is likely to be altered for a significant period of time to permanently. Other specific problems include the development of hydrocephalus, meningitis from persistent CSF leak, and an acquired strabismus. These events indicate the need for counseling of the family of the patient as well as the patient in the intensive care setting with plans for well organized follow-up. [37-40]

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A Digoxin Induced Epileptiform Seizure: An Unusual Toxic Manifestation

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ABSTRACT—A case of a 66-year-old woman with a documented generalized convulsion is presented. A work-up failed to reveal any other etiology for the seizure except digoxin intoxication. This unusual manifestation of digoxin toxicity is discussed.

The toxic manifestations of digoxin therapy are potentially large in number and varied. Included among these are several neurologic disorders. The more commonly seen neurologic side effects attributed to digoxin therapy include confusion, lethargy, psychotic behavior, and headaches. As far back as Withering,[2] convulsions have been listed as a potential manifestation of digoxin intoxication. A review of the literature, however, reveals few documented cases of digitalis induced seizures.[3] The case that follows represents a witnessed seizure in a patient with an elevated digoxin level.

Case Report

A 66-year-old woman was admitted to the Greenwich Hospital with a history of nausea and vomiting for several days. She had a long history of atherosclerotic heart disease, characterized by several myocardial infarctions, congestive heart failure, and chronic angina. A permanent pacemaker had been implanted 18 months prior to admission for paroxysmal complete heart block. Coronary artery bypass surgery had been performed several months prior to admission because of medically refractory angina. At the time of admission, she was on a regimen of digoxin 0.25 mgm daily, hydrocholorthiazide 50 mgm daily, amiloride 5 mgm daily, pronestyl 500 mgm q.i.d., and persantine 50 mgm t.i.d.

For several days prior to admission, the patient had experienced profound nausea and intermittent vomiting. Initially, this was accompanied by a low grade temperature and was felt to be due to a viral gastroenteritis. On the morning of admission, because of worsening symptoms, she came to the hospital. Up until the time of admission, she continued to take all of her medications.

Physical examination upon arrival in the hospital revealed a thin, chronically ill-appearing woman complaining of severe nausea. Her blood pressure was 110/68 mm Hg supine, it decreased to 90/60 mm Hg when she sat up. Her pulse was 74 and regular and increased to 84 in the upright position, and she was afebrile. Aside from the orthostasis, her exam was remarkable only for the cardiovascular exam which revealed a diffuse and displaced PMI, an S4 gallop, and a 2/6 systolic ejection murmur at the left sternal border. Her abdominal and neurological exams were normal. An admission EKG demonstrated normal sinus rhythm at a rate of 74 with evidence of an old anterior wall myocardial infarc-

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tion, but without change from her previous electrocardiogram. Laboratory studies revealed a normal CBC, a Na^+ of 138 mEq/L, a K^+ of 3.8 mEq/L, and a BUN of 26 mg/dl. An arterial blood gas on room air revealed a pH of 7.44, a PCO2 of 26 mm Hg, and a PO2 of 64 mm Hg. An infusion of D51/2NS with KC1 was begun and she was placed at bed rest. Soon after admission the patient was witnessed to have a grand mal seizure. She was noted to have regular pulse during, and immediately following the seizure. An electrocardiogram was obtained following the seizure and was unchanged from the earlier one and revealed no arrhythmias. A check of her pacemaker found it to be functioning normally in a demand mode, at a rate of 60 beats per minute.

A careful neurologic exam following the seizure, aside from some post ictal lethargy, was unremarkable. A CT scan of the head was performed with and without contrast and was normal. A lumbar puncture was also performed and was within normal limits. A digoxin level, obtained on Admission, was 3.0 ng/ml (normal = 0.8-2.0 ng/ml).

Based on the elevated digoxin level, it was decided not to initiate anticonvulsant therapy. An EEG was performed the following day and did not reveal any seizure activity.

Her subsequent course in the hospital was uneventful. There were no further seizures and no new neurologic findings developed. She was restarted on a lower dose of digoxin and in the ensuing three months no seizures have occurred.

Discussion

The incidence of digoxin toxicity has decreased over the last decade. The current estimates are that 5 to 15% of hospitalized patients on the drug are toxic.[4] This is clearly down from levels described in the past which reached as high as 30%.[5] The reason for this decline probably rests with increased physician awareness of digoxin pharmacokinetics, as well as the widespread use of serum determinations.

Nonetheless, toxicity does occur and the present case represents an unusual manifestation of this. Digitalis has been described to produce epileptiform activity on electroencephalograms in both rats and humans. Kerr,[6] has reported a case of digitalis induced epileptiform seizures. He further demonstrated an apparent correlation between serum digoxin levels and abnormalities on the electroencephalograms. In the case under discussion, the EEG was normal. This study was performed 24 hours after the seizure, presumably enough time to allow the serum digoxin level to normalize.

The mechanism of digitalis induced seizures is thought to be related to its effect on the neuronal Na^+/K^+ ATPase pump. By poisoning this pump an accumulation of sodium and calcium takes place intracellularly, resulting in heightened neuronal irritability.

Given the frequency of digoxin excess, the reported incidence of seizures is small. It is possible that many seizures are over-looked or misinterpreted as syncopal episodes resulting from digitalis induced arrhythmias. Notwithstanding this possibility, the question arises as to what factors, if any, predispose patients to develop seizures as a result of digoxin toxicity?

In conclusion, a case of a digoxin induced grand mal seizure is presented. Although the incidence, exact mechanism, and possible predisposing factors are not known, a serum digoxin determination is recommended in patients who present with seizures on digoxin therapy. This simple test may preclude a further costly evaluation, as well as unnecessary therapy.

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Arboviral Encephalitis: The Need for Clinical Suspicion in Connecticut

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In the summer and fall of 1983 human infection with two separate arboviruses occurred adjacent to the eastern and western borders of Connecticut. California encephalitis occurred in Dutchess County, New York State, and Eastern Equine Encephalitis occurred in Westerly, Rhode Island. Given the proximity to Connecticut, it seems reasonable to be prepared for the eventual appearance of cases here. The purpose of the present communication is to review the epidemiology of arboviruses, the history of these viruses in Connecticut, and to discuss their clinical manifestations in order to facilitate recognition. The discussion is presented at this time to anticipate the June to October period when arboviruses are active.

Epidemiology of the Arboviruses

The term arbovirus, a contraction of arthropod-borne, is epidemiologically based, suggesting the natural cycle between insects and animals. By and large it has been supplanted in textbooks of virology by a taxonomy based on the physical and chemical characteristics of viruses. Thus, Eastern Equine Encephalitis is in the alphavirus group of the Togavirus family. The California Encephalitis serogroup of viruses is in the Bunyavirus family. None the less, the term arbovirus is useful because it highlights the natural cycles. The cycle for Eastern Equine Encephalitis occurs in woody swamps or ponds, sometimes in proximity to salt water marshes. The mosquito vector in the natural cycle is Culiseta melanura and the animal reservoir is in birds, wild and penned. Man and horses are dead-end offshoots of the usual cycle. The mosquito vector to man has not been unequivocally defined. The distribution of the virus infection in the U.S. is the Atlantic seaboard and the Gulf Coast areas. There are several specific viruses within the California Encephalitis serogroup. Of these, the most frequent cause of human disease has been the La Crosse Virus. Jamestown Canyon Virus may also assume importance for humans. La Crosse Virus occurs endemically in woodland areas reflecting the breeding preferences of the vector, Aedes triseriatus. This mosquito breeds in water collected in basal tree holes, and, ironically, in discarded tires. The animal reservoir is in small woodland mammals. Again, infection of man is an offshoot. The majority of cases in the U.S. are in the upper Midwest and New York State. The two other major arbovirus causes of encephalitis in the U.S. are St. Louis Encephalitis and Western Equine Encephalitis. Cases of St. Louis Encephalitis have a very wide distribution in the U.S. but have not yet been found in Connecticut. Western Equine Encephalitis tends to produce clinical cases west of the Mississippi River.

Arboviruses in Connecticut

Despite extensive testing, no human case of arbovirus encephalitis in which the infection was initiated in Connecticut appears to have been identified. However, patients with arbovirus encephalitis, infected elsewhere, have been cared for in Connecticut medical facilities. Thus a young man infected during a trip to the West developed Western Equine Encephalitis on return home to Connecticut.[1] A case of California encephalitis from Westchester County in New York, and recently, a case of Eastern Equine Encephalitis from Rhode Island have been referred to the Yale-New Haven Medical Center.

Although no indigenous cases of Eastern Equine Encephalitis or California Encephalitis are known to have occurred in the state, the presence of each virus has been documented for years. Eastern Equine Encephalitis has

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been frequently isolated from mosquitos in Connecticut by the Yale Arbovirus Research Unit.[2] Epizootics in penned pheasants have occurred since 1938. Infection of horses has been surveyed with three documented in 1983. Viruses of the California Encephalitis serogroup have been found in mosquitos in Connecticut since 1966.[3] The reasons for the absence of transmission of Eastern Equine Encephalitis Virus and California Encephalitis Virus to man in Connecticut, despite the presence of the viruses, are unclear. None the less, the presence of human infections in adjoining regions suggests the need to be able to recognize the clinical manifestations of these diseases.

Clinical Manifestations of California Encephalitis

In the California Encephalitis serogroup La Crosse Virus has been the one most frequently associated with clinical illness. Ninety percent of La Crosse virus encephalitis cases are in children, 15 years or younger. It tends to be a rapidly evolving encephalitis[4] following an incubation period of three to seven days. The disease is usually ushered in by fever and headache with nausea and vomiting. Stiff neck is often found. Significant signs of encephalitis present themselves within the next two to four days. These include depression of the level of consciousness, the development of focal motor signs in some patients, and seizures in half of the patients. The seizures are most frequently generalized but in about a third of the patients they are focal in nature. Stabilization and resolution of the clinical signs usually occurs over the following week. Rapid reversal may help to distinguish it from Herpes Simplex encephalitis. The peripheral white blood count is often elevated. Neurodiagnostic tests support the diagnosis of encephalitis but are not specific. Thus the lumbar puncture reveals a moderate pleocytosis and the spinal fluid protein may be slightly elevated particularly after the fifth day of illness. The electroencephalogram is usually abnormal, frequently demonstrating bilateral slow wave activity. On occasion, the radioisotope brain scan has demonstrated a focal abnormality but more frequently it has been normal. Virologic diagnosis is most readily accomplished by the demonstration of a diagnostic rise in antibody between the acute and convalescent serum samples. Isolation of the virus from the cerebrospinal fluid is unusual. Treatment is symptomatic since no specific antiviral treatment exists. The management of seizures may be difficult. However, the outcome of the illness is usually benign with mortality under 1% and significant sequelae being rare. Non-specific residua of irritability and listlessness may require two to three months to clear.

Clinical Manifestations of Eastern Equine Encephalitis

Eastern Equine Encephalitis presents many contrasts to La Crosse encephalitis. It has a high mortality rate and does not have a clear predilection for any one age group. Fortunately it occurs much less frequently than La Crosse Encephalitis. The onset may be explosive, particularly in children, with fever, vomiting, stiff neck, and decreased level of consciousness.[5] Encephalitic manifestations of seizures, upgoing plantar responses and the rapid development of coma may ensue. A less explosive onset may also occur, particularly in adults. In this case, headache and fever may be present prior to the appearance of frank neurological signs. Some cases have been associated with a non-pitting edema in the periorbital areas. The course of the illness is often fulminant within a few days. Mortality occurs in over 50% and significant neurologic defects are frequently found in the survivors. Satisfactory recovery occasionally occurs, particularly in adults. The peripheral white blood count is usually elevated, including an increase in the percentage of polymorphonuclear cells. Examination of the cerebrospinal fluid reveals an increased opening pressure, elevated protein, and a pleocytosis. The pleocytosis often contains a predominance of polymorphonuclear cells throughout the acute course of the encephalitis. The electroencephalogram in such severe cases is abnormal with slow wave and spike activity. Viral diagnosis is most readily achieved by demonstrating a rise in the serum antibody between the acute and convalescent samples. Virus has been isolated from the blood, cerebrospinal fluid, and brain biopsy. Isolation is most likely to be successful in the first five days of the illness. In management, particular regard must be paid to raised intra-cranial pressure as well as to seizures. No specific antiviral therapy is available.

Conclusions

Although the viruses of Eastern Equine Encephalitis and California Encephalitis have been present for years, clinical cases in humans have apparently not developed in Connecticut. However, the continued occurrence of human cases of California Encephalitis in New York counties bordering on Connecticut and the first appearance of cases of Eastern Equine Encephalitis adjacent to the Connecticut border in Rhode Island, establishes the need to watch for these diseases here. The Connecticut State Virology Laboratories are anxious to determine if cases are in fact occurring in Connecticut. Acute and convalescent samples of serum, and samples of cerebrospinal fluid if available, should be sent even if there is only a modest suspicion of these diseases.

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Important Advances in Clinical Medicine

Epitomes of Progress—Preventive Medicine and Public Health

The Scientific Board of the California Medical Association presents the following inventory of items of progress in preventive medicine and public health. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in preventive medicine and public health that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Preventive Medicine and Public Health of the California Medical Association and the summaries were prepared under its direction.

Short-term Chemotherapy for Tuberculosis

The introduction of rifampin and its combination with isoniazid as initial therapy has made it possible to successfully treat tuberculosis in its various manifestations for less than 18 to 24 months. Administering isoniazid, 300 mg, and rifampin, 600 mg, once a day by mouth converts 90% of sputum-positive patients to a negative status within three months. Almost all others will have negative sputum cultures by the end of six months. By giving isoniazid and rifampin for a minimum of nine months, with the proviso that the final six months of treatment be accompanied by negative sputum cultures for *Mycobacterium tuberculosis,* almost all newly diagnosed patients will complete treatment between 9 and 12 months. Monthly visits with sputum examinations for acid-fast bacilli help determine the precise duration of therapy. Adverse drug reactions to isoniazid and rifampin are minimal. These can be recognized by clinical assessment and liver function tests done monthly.

Primary drug resistance has been recognized among initial sputum isolates from immigrants from Latin-American (12%) and Asian-Pacific (15%) countries. For this reason, it is prudent to begin therapy in Hispanic and Asian patients by giving not only isoniazid and rifampin but also a third antituberculous drug, namely ethambutol hydrochloride, 15 to 25 mg per kg of body weight, or pyrazinamide, 1.5 grams, once a day by mouth. These drugs should be taken until drug susceptibility tests are reported. For those patients with organisms susceptible to isoniazid and rifampin, the third antituberculous drug can be discontinued; for the rest, triple drug therapy should be continued throughout the treatment period. Isoniazid should not be discontinued despite in vitro resistance as it has a therapeutic effect on tubercle bacilli in vivo.

Relapses or recurrence of positive cultures for *M tuberculosis* occurring after the completion of appropriate chemotherapy are infrequent following short-term chemotherapy. Almost all relapses occur during the six months after completion of therapy. The organisms that reappear under these circumstances have the same drug susceptibility patterns that were present before initial chemotherapy. Reinstitution of antituberculous chemotherapy for at least a year is usually successful.

Short-term chemotherapy is also applicable to those patients who, for a variety of reasons, do not or cannot take their daily medicine on a voluntary basis. By identifying those patients through an initial compliance assessment—that is, behavioral, cultural, psychologic and other life-style factors that are frequently associated with noncompliance—a treatment program consisting of intermittent supervised chemotherapy can be designed that will ensure a successful outcome. Isoniazid, 15 mg per kg, and rifampin, 600 mg, are administered twice a week by mouth by a responsible person (family member,

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clinic personnel, community worker or the like). Where there is concern regarding initial resistance to isoniazid, either ethambutol (50 mg per kg) or pyrazinamide (2 to 3 grams) is given in addition to the isoniazid and rifampin. A treatment period of 9 to 12 months will suffice provided that the sputum cultures for acid-fast bacilli are consistently negative for the final 6 months. Despite the high incidence of patients with preexisting liver disease within the noncooperative group, adverse liver reactions due to isoniazid, rifampin, and pyrazinamide are remarkably infrequent.

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Exposure of Expectant Mothers to Cytomegalovirus Infections

Human cytomegalovirus (CMV) infections are common worldwide. The epidemiology of this virus has not been completely delineated but it is known that transmission from person to person requires intimate contact. Among adults, the primary route of transmission is by intimate (oral or sexual) contact. Most cytomegalovirus infections are asymptomatic or mild.

Infection with cytomegalovirus has particular significance for pregnant women. The virus can infect the fetus in utero following a primary infection in the mother and, unlike rubella, also by reactivation of latent maternal cytomegalovirus. The risk of manifest congenital disease at birth appears to be largely associated with a mother's first (or primary) infection during pregnancy but the relative contribution to fetal damage by reactivated maternal cytomegalovirus infections has yet to be defined. In the United States 0.5% to 2.2% of all newborns are congenitally infected as shown by viral excretion at birth but most of these infected infants show no clinical signs of impairment at delivery. About 10% of these infections (about 1 per 1,000 births) result in some overt congenital cytomegalovirus disease at birth, but some of the asymptomatic congenital infections may produce effects detectable only later in life.

The results of several studies suggest that from 3% to 28% of all pregnant women in the US shed cytomegalovirus from their cervix by the third trimester of pregnancy. The virus has also been detected in the breast milk of 13% of women with cytomegalovirus antibodies. Such viral shedding is thought to be due predominantly to the reactivation of latent infection during pregnancy. Infants born to mothers shedding this virus may be infected connatally—that is, during labor or at birth—or postnatally. Most connatal and postnatal infections, like those acquired in utero, are asymptomatic, but some of these infections may conceivably produce subtle effects, the long-term results of which have not been well documented. Studies in the US also indicate that up to 30% of all children acquire cytomegalovirus infections by 3 years of age. Avoiding or reducing the risk of exposure to cytomegalovirus is difficult because of the large number of asymptomatic virus shedders in the general population.

Whether women who provide care to any group of infants and children have a greater risk of acquiring a primary infection with this virus than women not so employed has not been established. The most important routes of cytomegalovirus transmission from children to adults are apparently via contact with urine or saliva of virus shedders, for example, through kissing or poor personal hygiene after handling soiled diapers. Thus, nursery and other child care staff who are in contact with known infected infants and who adhere to routine patient care practices such as handwashing should not be at increased risk of acquiring a cytomegalovirus infection.

Women of childbearing age should be informed that this virus is ubiquitous and that prevention of infection from infants and children in any setting (home or occupation) is best accomplished by observing good personal hygiene. These women should also be advised that this virus is of relatively low infectivity, and in contrast to the transmission of rubella and rubeola infection, intimate contact is usually required to transmit it. Antibody testing programs for women who are routinely in close contact with children cannot be recommended at the present time, since there is no information to indicate (or suggest) that such a program would reduce the risk of congenital damage to infants infected with cytomegalovirus.

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Car Passenger Injuries and Child Restraints

The use of appropriate restraining devices (car seats and safety belts) for child car passengers is truly an idea whose time has come. Few health service agencies, such as hospitals, clinics, medical or dental offices, pharmacies or health departments, actively promoted these devices until a short while ago. For children under 15 years, car passenger injuries represent the single leading cause of death in the United States, almost 2,000 fatalities per year.

The younger a child, the more vulnerable he or she is to severe injury or death. Considering the anatomic proportions of children, this finding is not surprising: a relatively higher center of gravity makes a child, when unrestrained, serve as a projectile hurled inside or outside a car when it is stopped by a crash or sudden braking. The "typical" child victim is a 1-year-old who rode unrestrained in the front seat of the family car, and the injury occurred during the daylight hours and in ordinary weather and road conditions.

There is no question that child restraints provide significant protection; unrestrained children are more than ten times as likely to sustain severe injury or death. Tennessee, the first state to enact mandatory child restraint legislation in 1978, reports a provisional 50% reduction in fatalities. About 30 other states have recently enacted similar legislation mandating car seat or safety belt use by young children.

Through education of their parents, children should be protected against car passenger injuries. Ideally this activity should be initiated during the prenatal period and proceed on through infant restraints to include the use of safety belts by school-age children. This simple, sensible and safe practice will not be easy to implement universally but can be accomplished through a combination of health education, legislation and the development of an increased personal sense of health and safety.

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Office Treatment of Alcoholism

Most physicians have been trained in public hospitals to recognize alcoholism by a patient's end-stage liver disease or other serious sequelae of heavy drinking. Patients who are obviously alcoholic represent only 5% or so of those who will go on to die an average of ten years prematurely because of their alcohol-related problems.

The average alcoholic person is a blue-collar or white-collar worker or a homemaker who drinks too heavily on evenings or weekends or experiences short periods each year when alcohol problems escalate. In these persons, who compose 15% to 20% of the patients seen in practice, cirrhosis rarely develops (seen in only 15% of alcoholic persons), and they are unlikely to enter a physician's office in an intoxicated state. The fall of blood alcohol concentrations to zero on an almost daily basis results in a moderate to mild withdrawal syndrome that, for 95% of these persons, causes tremor, anxiety and a flulike feeling.

Recognition of this average middle-class alcoholic person is important to clinicians because such patients are not likely to respond in a predictable way to therapeutic intervention if they continue drinking. Patients usually have nonspecific complaints, perhaps request a physical examination, and are likely to have mild hypertension (about 140/90), mild elevations in any one or more or a number of laboratory values (uric acid, γ-glutamyl transferase, triglycerides, mean corpuscular volume) or have symptoms of insomnia, impotence or depression. The diagnosis is made by asking a patient (and spouse, if appropriate) about the pattern of life problems and then determining whether alcohol was a contributor. These problem areas include a family (a separation or divorce related to alcohol), police (two or more alcohol-related arrests or accidents), job (an alcohol-related loss or layoff) and health (physical evidence that alcohol intake had harmed health, including a history of alcohol withdrawal). Once alcoholism has been identified, confrontation entails reminding patients that they are responsible for their own actions, pointing out ways in which alcohol use has significantly interfered with their life, noting that a long and healthy life will require abstinence and referring them to a treatment program or Alcoholics Anonymous (or both).

The prognosis in alcoholism is good. The chances that a patient will achieve and maintain abstinence for an extended time (longer than a year) increase with the patient's level of stability before entering care. Thus, a person who has an intact family, a job or relevant job skills and an absence of drug problems or non-alcohol-related police difficulties has a 70% chance of being abstinent for one to two years.

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Screening for Colorectal Cancer

Colorectal cancer is the second most common type of cancer (excluding skin cancer) in the United States. In 1983 there will be an estimated 126,000 new cases

(87,000 colon and 39,000 rectal) with about 58,000 deaths.

The American Cancer Society has issued the following guidelines for colorectal cancer checkups:

- Men and women over 50 years of age should have a test for occult blood in the stool every year;
- men and women over 50 years of age should have annual sigmoidoscopic examinations until two consecutive examinations are normal and thereafter every three to five years, and
- men and women over 40 years of age should have a digital rectal examination yearly.

Persons who are at a high risk of colorectal cancer developing should receive more frequent and intensive examinations beginning at an earlier age. High-risk groups include persons with a history of adenomatous colon polyps or prior colon cancer, Gardner's syndrome, ulcerative colitis, familial polyposis or a family history of colorectal cancer.

The National Cancer Institute's consensus report states that the stool blood test should not be used as yet for screening, until the outcome of ongoing clinical trials shows a decrease in colorectal cancer mortality. The Canadian Cancer Society recommends that the screening use of stool blood test be used only for persons at high risk.

One must realize that most but not all colorectal cancer patients will have occult blood in the stool and that some but not all precancerous colorectal lesions (for example, adenomatous polyps) will bleed; other nonneoplastic conditions may give a positive test for blood. One must also accept the cost and risk of the workup when occult blood is found in stool specimens, to be able to detect colorectal cancer at an earlier stage and improve the prognosis. I favor the American Cancer Society's recommendations for the present instead of awaiting the results of clinical trials.

The International Workgroup on Colon Rectal Cancer has recommended that fecal occult blood testing be done annually beginning between the ages of 40 and 50 years.

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Prevention of Hepatitis B Virus Infections From Mothers to Infants

While relatively uncommon in the United States, chronic infection with hepatitis B virus (HBV) may be found in up to 15% of the population in many developing countries. A significant proportion of these infections occurs as a result of mother-to-infant transmission. Persons chronically infected with HBV, especially those infected at birth or early in life, are at increased risk of subsequent liver disease such as chronically active hepatitis, cirrhosis and primary hepatocellular carcinoma.

In California alone (an area of low incidence), an estimated 3,000 to 5,000 women who are positive for hepatitis B surface antigen (HBsAg) give birth each year. Most mother-to-infant infections seem to occur at the time of delivery (connatal) or shortly thereafter, rather than transplacentally. The probability of exposed neonates becoming HBV carriers can be greatly reduced by administering hepatitis B immune globulin. The Public Health Service Immunization Practices Advisory Committee (ACIP) recommended in 1981 that all infants born to HBsAg-positive mothers should be given 0.5 ml of hepatitis B immune globulin immediately after birth and at three and six months. The Committee on Infectious Diseases of the American Academy of Pediatrics has made a similar recommendation.

In June 1982 the ACIP recommended that infants born to HBV-infected mothers should also receive hepatitis B virus vaccine, in addition to the three doses of hepatitis B immune globulin, inasmuch as these infants may continue to be at risk of infection from their mothers and other possible carriers in the household. The optimal timing for giving the vaccine in conjunction with hepatitis B immune globulin has not yet been established. Until additional data are available, however, the ACIP has recommended that immunization with hepatitis B virus vaccine should be started at three months of age, or shortly thereafter.

To carry out appropriate prophylactic measures in the delivery room, it is necessary to know before delivery whether the mother has the hepatitis B surface antigen. The HBsAg carrier rate in the US population ranges from 0.1% to 0.5%. Much higher HBsAg carrier rates are found in persons from hyperendemic hepatitis B virus areas of the world, such as Asia, Subsaharan Africa and the Pacific Islands. Persons of Asian ancestry born in the United States appear to maintain relatively high HBsAg carrier rates. There are thus clear indications for doing routine prenatal HBsAg testing of women who are members of groups with HBsAg carrier rates of 1% or more. In addition to the ethnic minorities already mentioned, these groups include women who have acute or chronic liver disease, frequent occupational exposure to blood, household or sexual contacts of known HBsAg carriers and women with a history of injecting illicit drugs.

The prevention or modification of hepatitis B virus infections in infants deserves high priority as there is no present cure or treatment for the chronic HBsAg carrier state once it is established. Additionally, failure to identify pregnant carriers in the known high-risk groups can expose health care providers to an increased risk of nosocomial hepatitis B and to possible legal action on behalf of those infants in whom the chronic carrier state might develop because of the failure to provide any prophylaxis.

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Pesticides as a Public Health Concern in California

California leads the nation both in the volume of pesticides used and in the number of pesticide-related illnesses. In 1981 the statewide use of 218 million kg (480 million lbs) of pesticides, 78% of which was for agriculture, the remainder for home, garden, structural and industrial use. Last year, 1,388 illnesses related to occupational exposure to pesticides were documented in the state, 48% of which involved systemic symptoms, the rest being skin and eye conditions. This information is based on physicians' reports of pesticide illness and investigations by agricultural and public health agencies. The State Health and Safety Code requires that any physician "who knows, or has reasonable cause to believe, that a patient is suffering from pesticide-related illness" must report the case to the local health officer within 24 hours; also, in work-related illness, a "Physician's First Report" of illness must be filed within seven days. Failure to comply with the reporting requirement renders the physician liable for a civil penalty of $250.

The high-risk occupations for systemic pesticide illness are mixing, loading and applying of pesticides, particularly fumigants and organophosphates. Also, workers harvesting fruit and vegetable crops accounted for 362 illnesses. The problem of field worker poisoning is most pronounced in coastal areas where highly toxic organophosphates (for example, mevinphos) and carbamates (for example, aldicarb) are applied to row crops shortly before harvest. The State Agriculture Code for specific pesticides requires that workers not reenter treated fields until pesticide residues have degraded to levels that should not result in acute worker illness. However, dermatitis, the most common field worker illness, and systemic poisonings from dermal absorption of organophosphates do occur because workers are sent into fields before the reentry interval expires.

Clinicians who wish a handbook review of the subject may request the manual *Recognition and Management of Pesticide Poisonings* from the Environmental Protection Agency. The definitive text on the subject is Wayland Hayes' recently published *Pesticides Studied in Man.*

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International Travel Requirements

Travelers who see physicians before traveling abroad usually do so because of the perceived need for a required immunization. More often than not these immunizations are not required, but other immunizations, chemoprophylaxis and advice are much more important for a traveler's health.

Only two immunizations can be legally required of civilian travelers. (Smallpox has been officially eradicated with the last reported endemic case in 1977, and no country presently requires smallpox immunization.) Countries requiring immunization against cholera or yellow fever (or both) can refuse the right of entry to travelers who have neither a valid immunization recorded on the International Certificate of Vaccination nor a written statement from a physician indicating why immunization was contraindicated. An annually updated list of required immunizations by country is provided by the Public Health Service in the Information for International Travel Monograph, available from the Centers for Disease Control, 1600 Clifton Rd., NE, Atlanta, GA 30333.

The risk of cholera in travelers with normal gastric acid is minimal. Nevertheless, many countries require cholera vaccine for all travelers or for those coming from a cholera endemic area, therefore, cholera immunization is often given to travelers to prevent border hassles. One injection of the presently available killed cholera vaccines will meet international requirements, and, after a six-day waiting period, is valid for six months. Cholera immunization is not recommended or required for infants.

Yellow fever, limited to tropical Africa and South America, can be prevented by a single injection of attenuated 17D live virus vaccine; the certificate of vaccination is good for ten years after a ten-day waiting period. Yellow fever vaccine is not recommended for infants less than 1 year of age, for pregnant women or for immunocompromised persons. Correct handling of the vaccine, described in detail on the label, is essential.

In addition to immunizations that may be required, all children should have their childhood immunizations up to date. Adults should be urged to have a tetanus booster and live oral poliovirus vaccine if they have not been immunized with these agents within the past ten years. Adults who have not previously received oral poliovirus vaccine or whose polio immunization record is uncertain should receive parenteral (killed) poliovirus vaccine to avoid the small risk (1 per 11 million doses) of paralytic poliomyelitis associated with live oral poliovirus vaccine. Travelers to developing countries may also be given typhoid vaccine: three doses are recommended but a single dose, all that many travelers have time for, offers some protection. γ-Globulin is recommended to reduce the risk of hepatitis A. When necessary, all active immunizations can be given at separate sites on the same day. γ-Globulin, however, may interfere with antibody response to active immunization and should be given at least two weeks, and perferably four, after the vaccines. Because γ-globulin protection wanes over time, it should be given only a few days before departure.

Other vaccines occasionally recommended for travelers according to itinerary and life-style are plague, rabies and bacille Calmette-Guérin (BCG) against tuberculosis; few persons who travel for pleasure need these vaccines. Typhus vaccine is not recommended for travelers, nor is it available in the United States.

Few travelers come to a physician seeking antimalarial drugs. Physicians must match the itinerary against the malaria transmission by country data provided in the Information for International Travel Monograph. For most travelers to most malarious areas a weekly (300 mg base) dose of chloroquine throughout the entire period of exposure and for six weeks thereafter will suffice. This should be started one to two weeks before exposure to be sure that the medication is tolerated. Except for a few persons who are chloroquine intolerant (vomiting and malaise being the most common side effects), chloroquine can be given safely to all travelers, including children and pregnant women. Chloroquine-resistant falciparum malaria is seen in Southeast Asia and some parts of South America and East Africa. Travelers to these areas, as detailed in the monograph, should receive Fansidar (Hoffmann-La Roche) in addition to chloroquine. Fansidar is a newer antimalarial agent, each tablet containing 500 mg of sulfadoxine and 25 mg of pyrimethamine. One tablet of Fansidar is taken weekly at the same time and for the same duration as chloroquine. Fansidar is not recommended for young children or pregnant women.

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Toward the Elimination of Measles

Before introduction of the measles vaccine in 1963, 500,000 cases of measles (rubeola) were reported yearly in the United States, though the actual case number was much higher. Also, 500 deaths and 1,000 cases of neurologic damage occurred yearly. In the first few years after the vaccine came into use measles incidence dropped 90%, but it declined no further through most of the 1970s. The reasons were that only 60% of US children were being immunized and that vaccine failure was common, due to the use of an ineffective inactivated vaccine in the early years, failure by some to adequately protect the live vaccine from heat and light and administration of live vaccine at too early an age. (In children under age 13 months, persisting maternal antibody may interfere with immunization.)

Measles has no nonhuman reservoir and no carrier state, and the measles vaccine confers long-term, probably lifelong, immunity. Consequently, in 1978 the Centers for Disease Control launched a campaign to eliminate continuing indigenous measles transmissions from the US by late 1982, based on a strategy of near-universal immunization and intense disease surveillance and outbreak control. We have come remarkably close to this goal. In 1982 only 1,700 cases were reported nationwide, a 99.7% drop from prevaccine era incidence. In all, 94% of US counties remained entirely measles-free in 1982. The principal reason for this achievement was enactment and strengthening of laws requiring measles immunization for entry to schools and child care centers in all 50 states during the late 1970s. Current surveys indicate that each year 96% of the nation's kindergarten pupils have satisfactory evidence of measles immunization.

Sporadic measles outbreaks still occur, however, particularly in large urban populations repeatedly exposed to measles importations and with lower immunization levels in older school pupils, who entered school before the immunization laws were strengthened. Several states are currently acting to improve the protection of older pupils, requiring that they provide schools with records showing at least the month and year of immunization with live measles vaccine given no earlier than the first birthday. In addition to giving measles vaccine to children at age 15 months and to all patients age 25 years and under who have not already been immunized or had the disease, physicians are urged to reimmunize those who received vaccine before their first birthday, when the seroconversion rate may have been only 80% to 85% or even lower, compared with 95% for immunization at older ages. Some authorities also recommend reimmunizing certain children previously immunized between 12 and 13 months of age.

Another major reason for the recent decline in measles incidence has been the public health effort to locate foci of continuing measles transmission and to eradicate these foci by prompt ring immunization. Physicians are urged to report immediately to county health departments by telephone all cases of measles, suspected measles and generalized rash with fever, without waiting until a definite diagnosis is made. Health departments can then promptly investigate and, if a focus of measles is found, define a zone or risk around the case(s) and immunize and isolate susceptible persons within that zone.

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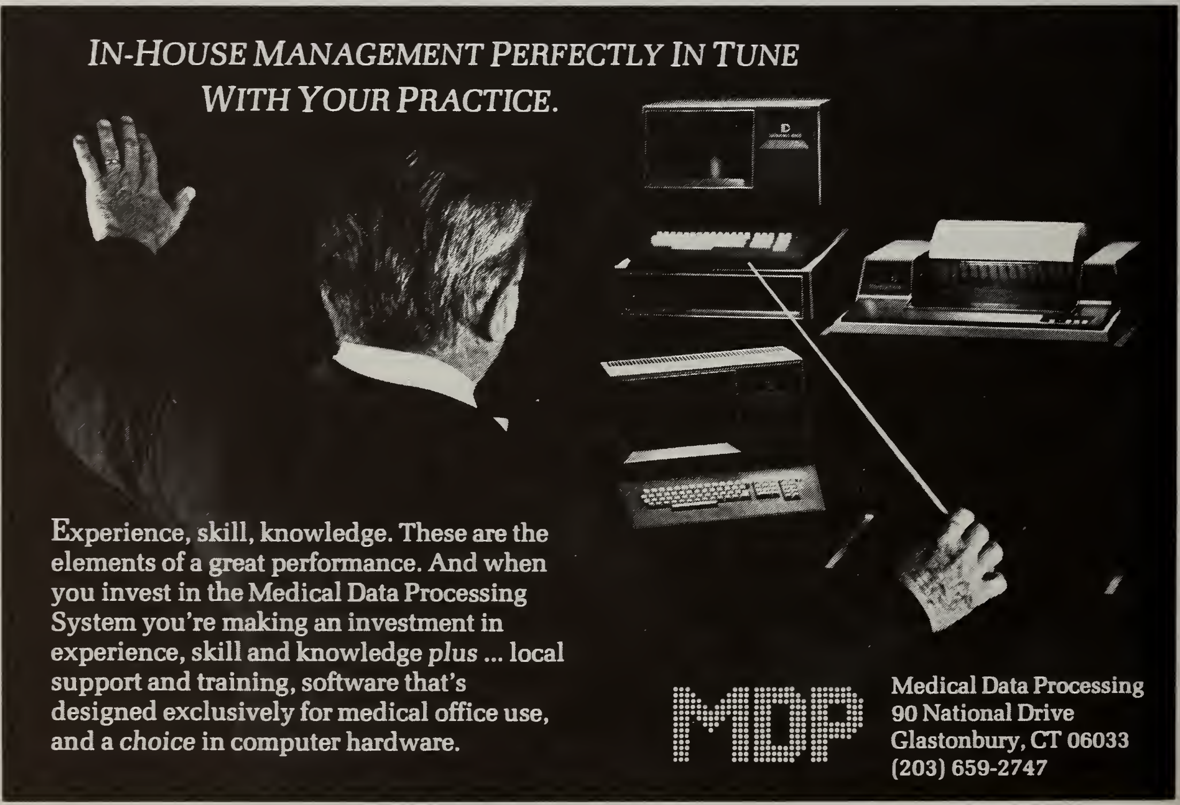

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Nonsmoking in Hospitals

AMA COUNCIL ON SCIENTIFIC AFFAIRS

Substitute Resolution 146 (A-81), adopted by the House of Delegates, called for the AMA to "establish suggested guidelines for hospitals to use relative to smoking on hospital premises." The implementation of Substitute Resolution 146 was referred to the Council on Scientific Affairs. In order to develop appropriate guidelines, the Council studied the following pertinent issues:

1. the effects of tobacco smoke on the nonsmoker (involuntary or passive smoking):
2. the fire hazards of smoking in hospitals;
3. public attitudes on restricting smoking in public places;
4. the nature and prevalence of current hospital smoking policies; and
5. relevant AMA policy.

On the basis of this study, the Council submits the following report to the House of Delegates.

Introduction

Laws and regulations that restrict smoking in public places are becoming increasingly common. A number of factors account for this trend, including greater knowledge of the health hazards of involuntary smoking, a declining percentage of the population who smoke, and the growing propensity of nonsmokers to assert their right to a smoke-free environment.

Among the many public places where smoking has been restricted, hospitals warrant special consideration. First, hospitals more than any other place should offer a safe, health-promoting environment. Institutions that seek to prevent and cure disease and relieve pain and suffering should not at the same time ignore unhealthy practices that exist on their own premises.

Second, the key inhabitants of hospitals—patients—are uniquely susceptible to the hazards of smoking. Many patients are particularly sensitive to the effects of involuntary smoking by virtue of the disease(s) from which they suffer. They and others also may be unable to avoid exposure to secondhand smoke, or escape from smoking-related fires, due to their physical incapacity.

Finally, patients in the hospital are often in a state of psychological debilitation. This compromises their ability to seek relief from tobacco smoke, which may require stressful interaction with roommates or visitors, or inconvenient solicitation of aid from hospital staff.

The Health Effects of Involuntary Smoking

No discussion of restricting smoking in public places would be complete without consideration of the effects of tobacco smoke on the nonsmoker. This report thus offers a convenient opportunity to review the growing body of knowledge on the subject since last reviewed by the AMA four years ago.[1]

Although there still are many unanswered questions regarding the degree of risk associated with involuntary smoking, research during the last decade has yielded steadily accumulating evidence indicating tobacco, smoke as a significant health hazard to the nonsmoker. This trend may be compared to the way in which the dangers of voluntary cigarette smoking were elucidated in the 1940s, '50s, and '60s. At one time, the relationship between cigarette smoking and death and disease was controversial. Today, this is no longer so.

The health hazards of involuntary smoking have been reviewed in detail in the Surgeon General's 1979 Report on Smoking and Health,[2] and more recently by Shephard.[3] They may be conveniently considered in three separate categories: the effects on sensitive populations, on healthy adults, and on the fetus.

Sensitive Populations

Those with cardiovascular and chronic pulmonary diseases are particularly prone to suffering ill effects from exposure to tobacco smoke. Patients with angina pectoris have reduced exercise tolerance after exposure to tobacco smoke at levels commonly found in public places. One study showed that the mean time of exercise until the onset of angina decreased by 22 percent in a well-ventilated room, and 28 percent in an unventilated room.[4] This ef-

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This report is not intended to serve as a standard of medical care: standards of medical care are determined locally and are constantly subject to change and are established on the basis of all the several facts of the individual case.

EDITOR'S NOTE: This is a report of the AMA Council on Scientific Affairs to the House of Delegates at the Interim Meeting of the AMA in Los Angeles, Dec. 1983.

fect is probably caused by elevated carboxyhemoglobin levels primarily, and perhaps to a less extent by the pharmacologic effects of nicotine. Similarly, a double-blind, randomized study demonstrated that carbon monoxide inhalation (comparable to that of involuntary smoking) in patients with angiographically documented iliofemoral occlusive arterial disease reduced the exercise time required to provoke claudicant pain by 17 percent.[5] Finally, carbon monoxide inhalation in a group of patients with chronic obstructive pulmonary disease (COPD) reduced the exercise time necessary to induce severe dyspnea by 33 percent.[6]

The significance of these studies on the issue of smoking in hospitals is obvious. Patients in the hospital are among the most sensitive to the deleterious effects of involuntary smoking, yet are often unprotected in this regard. The number of patients with such diseases, it should be noted, is not insignificant. Approximately five million Americans have ischemic heart disease.[7] More than a million Americans aged 40 to 65 years are partly or wholly disabled by COPD.[8] Foreign studies have found the prevalence rate of lower-extremity arterial insufficiency to be about two percent in middle-aged men, as determined by clinical examinations and/or physiological function tests.[9]

Infants and young children represent another special population that is particularly sensitive to the effects of involuntary smoking.[3] Several investigators have found a statistically significant relationship between parental smoking habits and childhood respiratory illness (common colds, influenza, bronchitis, and pneumonia). This association appears to be dose-related (stronger when both parents smoke, and varying with the total daily cigarette consumption), and is independent of parental lung disease, social class, and birth weight. Moreover, studies have also shown a correlation between maternal smoking and sudden infant death syndrome (SIDS). It is unclear, however, to what degree the relationship with SIDS may result from maternal smoking during pregnancy. Finally, the possible adverse effects of maternal smoking on lactation provide another potential risk to this group. Although studies have established a direct dose-response relationship between the number of cigarettes smoked and the level of nicotine in breast milk, the overall effect of maternal smoking on the adequacy of lactation and the health of lactating infants is unknown.[2]

Those with asthma or allergies comprise a third group that is more likely to suffer from secondhand tobacco smoke, which often precipitates or aggravates allergic symptoms.[3] The effect seems to be related more to irritation of sensitized airways than to a true allergic response. An estimated 35 million Americans have allergic disease, including 8.9 million with asthma.[10]

Healthy Adults

Irritant Effects

The first evidence suggesting that healthy adults may be adversely affected by involuntary smoking dealt with tobacco smoke's irritant effects. An early study by Speer[10] in 1968, and a more recent study by Shephard and his associates[3] a decade later, investigated the subjective response to tobacco smoke. Their results are shown in Table 1.

These two studies do not show close correspondence, but they nevertheless demonstrate that a large percentage of the general population reportedly suffers from a wide variety of irritant effects of tobacco smoke. Although surveys of subjective symptoms are inherently imprecise, one study showed a strong correlation between the various types of eye irritation induced by experimental exposure to cigarette smoke, some of which are more objective (e.g., blinking rate, tear flow) than others (e.g., itching).[12]

Effect on Small Airways

In March 1980, White and Froeb[13] published results showing that the effects of secondhand tobacco smoke on

Table 1
MOST FREQUENT SYMPTOMATIC RESPONSE TO INVOLUNTARY SMOKING

	Percentage Reporting Symptom			
Symptom	*Allergic Nonsmoker* (*N*=191)*	*Nonallergic Nonsmoker* (N=250)*	*Nonsmoker* (N=440)**	*Ex-smoker* (N=93)**
Eye irritation/ stinging eyes	73.3	69.2	46.6	27.9
Nasal symptoms (e.g., coryza)	67.1	29.2	2.5	1.0
Headache	46.0	31.6	13.0	8.6
Cough	46.0	25.2	–	–
Sore throat	23.0	5.6	–	–
Wheezing	22.5	4.0	2.7	2.1
Phlegm	–	–	0.7	1.0
Nausea	15.2	9.2	8.6	11.8
Dizziness	5.3	6.4	1.8	4.3
Other	–	–	7.7	6.4

*Source: Speer[11]
**Source: Shephard,[3] p. 68

the healthy nonsmoker may extend beyond simple irritation. In a study of 2100 subjects divided into experimental and control groups, they found that long-term (20 years or more) involuntary smoking in the workplace is associated with disease of the small airways of the lung, as measured by forced mid-expiratory flow rate (FEF 25-75%) and forced end-expiratory flow rate (FEF 75-85%). The difference in these measurements between nonsmokers chronically exposed to tobacco smoke and those not exposed was highly significant ($p = 0.005$). Moreover, the degree of impairment was not significantly different from that seen in light smokers (1-10 cigarettes per day for more than 20 years) and smokers who did not inhale ($p = 0.005$).

A similar study in eight towns throughout France looked at the effect of involuntary smoking in the home environment.[14] It compared the FEF 25-75% in 2812 wives who never smoked in relation to the smoking habits of their husbands. The 1863 whose husbands did smoke had a significantly lower FEF 25-75% than wives whose husbands did not smoke ($p = 0.03$). The difference became highly significant ($p = 0.004$) in women 40 years of age or older (i.e., after about 15 years exposure), and persisted in all social classes and in the various towns studied.

Finally, Tager et al[15] showed that children whose parents smoked had a lower FEF 25-75% than those who lived in households where smoking did not occur. The relationship was dose-related: the pulmonary function scores of the children studied were inversely proportional to the number of parents who smoked in the household. While this study deals with a "sensitive population" as discussed above, it nevertheless, supports the association between involuntary smoking and small airways disease in the general population.

The relationship between involuntary smoking and small-airways disease is of concern, even though such impairment may be asymptomatic. This is because small-airways disease, which is the first pathologic change seen in early smokers,[16] may be a precursor of disabling COPD.

Effect on the Risk of Lung Cancer

Even more worrisome is the possibility that involuntary smoking may increase one's risk of developing cancer. This concern is based on:

1. the presence of potent carcinogens in sidestream smoke (smoke released from the cigarette between active puffs), which are often at significantly higher concentrations than similar chemical constituents of the filtered, mainstream smoke (smoke actively inhaled);
2. the established dose-response relationship between voluntary cigarette smoking and lung cancer, as well as the absence of evidence establishing a threshold for effect; and
3. recent epidemiologic studies of the relationship between lung cancer mortality in nonsmoking wives and the smoking behavior of their husbands.[17]

Two examples of carcinogens present in sidestream tobacco smoke are nitrosamines and benzopyrenes. Brunnemann et al,[18] found that the sidestream smoke of cigarettes contains 10 to 40 times higher amounts of four measured volatile nitrosamines than the mainstream smoke of the same cigarettes. Likewise, the concentration of benzo(a)pyrene (a polycyclic aromatic hydrocarbon) in sidestream smoke is 3.4 times higher than in mainstream smoke.[17] It is interesting to note that the fire retardant Tris, whose use has been banned by the federal government, has one-tenth the experimental carcinogenic potency of benzo(a)pyrene.[19]

Based on studies of lung cancer risk in men exposed to the benzo(a)pyrene of coal gas, it has been estimated that "regular and fairly heavy exposure to environmental tobacco smoke" might increase the risk of lung cancer among nonsmokers by one-third, or about two cases of lung cancer per 100,000 per year.[20] This calculation does not take into account the presence of carcinogens other than benzo(a)pyrene, which is the most studied, but not necessarily the most important, hydrocarbon in sidestream tobacco smoke.

Even without epidemiologic data, the presence of such toxins in sidestream smoke carries ominous implications. Indeed, their occurrence led the AMA Board of Trustees to conclude, in a report adopted by the House of Delegates in December 1979, "importance of potent carcinogens contributing to mutagenesis and possible malignancy, while it cannot be easily quantitated for the passive smoker, is probably not insignificant."[1]

Since the adoption of the Board report, epidemiologic studies have examined the relationship between lung cancer mortality in nonsmoking wives and the smoking habits of their husbands in Japanese,[21] Greek,[22] and American[23] populations. The Japanese and Greek studies both showed a statistically significant, dose-response relationship between lung cancer mortality in nonsmoking wives and spousal smoking habits. The American study, on the other hand, showed a correlation that was neither statistically significant nor dose-related.

The Surgeon General's 1982 annual report on smoking and health[17] carefully considered the strengths and weaknesses of each of these three studies. Its conclusion was as follows:

> Thus, each of the three epidemiologic studies published to date shows an increased risk of lung cancer with involuntary smoke exposure. The results were statistically significant in two of the three studies, which also found a dose-response effect. The evidence currently available suggests that involuntary smoke exposure may increase the risk of lung cancer in nonsmokers, but limitations in data and study design do not allow a judgment on causality at this time.

Finally, a study by G. H. Miller[24] on the incidence of lung cancer in the Amish offers suggestive evidence that involuntary smoking may play a role in carcinogenesis. He found that no cases of lung cancer were reported from 1971 to 1977 among nonsmokers in a population of 12,000 Amish in Lancaster County, Pennsylvania. Based on the incidence of lung cancer among non-Amish in the same county, and the fact that 10 percent of cases of lung cancer occur in nonsmokers, Miller calculated the predicted incidence of lung cancer in this group of nonsmoking Amish to be 1.2 cases. He concluded that the difference between the predicted and observed incidence of lung cancer in nonsmoking Amish could be attributed to their smoke-free environment. Since very few Amish smoke, and since they rarely intermingle with the non-Amish population, their level of involuntary smoking is minimal.

Miller considered and dismissed other factors that might account for the difference (e.g., stress, heredity, environmental pollution). Nevertheless, the sample size studied was small. The results, while intriguing, therefore offer only suggestive evidence.

In summary, studies have shown that healthy adults exposed to secondhand tobacco smoke suffer irritant effects, are more likely to develop small-airways disease, and may be at increased risk of acquiring lung cancer. When considering restrictions on smoking in hospitals or other public places, one might conclude that the evidence now available ought to shift the burden to opponents of such regulation to document that involuntary smoking is not deleterious to health.

The Fetus

The fetus represents a special case of susceptibility to the effects of involuntary smoking that perhaps warrants consideration apart from that of other sensitive populations. In the first place, the fetus is at the most primitive (and sensitive) stage of human development. Any deleterious effects of involuntary smoking on the fetus are thus more likely to be severe or long-lasting. If the effect is fatal, the victim dies before it is born. Secondly, the fetus is wholly incapable of avoiding exposure to the constituents of tobacco smoke, as opposed to most other sensitive populations (the infant is another exception). Finally, the fetus is liable to suffer from secondhand smoke (maternal voluntary smoking) as well as "thirdhand" smoke (maternal involuntary smoking).

The effects of maternal smoking on the fetus have been reviewed in the Surgeon General's 1980 report of smoking and health, entitled "The Health Consequences of Smoking for Women." The findings of the Surgeon General are summarized below. While the mechanism underlying these effects is poorly understood, experimental data implicate the hypoxic effects of carboxyhemoglobin, the pharmacologic effects of nicotine, the mutagenic effects of polycyclic aromatic hydrocarbons, and the metabolic effects of cyanide and thiocyanate. To the extent that heavy involuntary smoking can cause exposure to these chemical constituents at levels that approximate those occurring in light voluntary smoking, even the fetuses of nonsmoking pregnant women may be at risk.[26,27] As such, these data have special relevance to the question of restricting smoking in hospital maternity wards and obstetrical clinics.

Birth Weight and Fetal Growth

Women who smoke during pregnancy give birth to babies who weigh, on the average, 200 grams less than those born to nonsmoking women. The importance of this effect lies with the fact that birth weight is a good overall indicator of prenatal development, and has a major influence on perinatal and neonatal mortality rates. The influence on perinatal and neonatal mortality rates. The relationship is independent of all other factors that are known to influence birth weight, including race, parity, maternal size, socioeconomic status, sex of the child, and gestational age. The association is dose-related: the more the mother smokes during pregnancy, the lower the birth weight. It appears to be mediated by a direct growth retarding effect on the fetus rather than by reduced maternal appetite, eating, or weight gain. Furthermore, the growth retardation extends to all dimensions of birth size, including body length, and head and chest circumference.

Fetal and Infant Mortality

The incidence of spontaneous abortion, fetal death, and neonatal death correlates directly with increasing levels of maternal smoking during pregnancy. Moreover, maternal smoking may interact with other perinatal risk factors to enhance the danger to the fetus or newborn. The excess fetal and neonatal deaths seem to be related to problems of pregnancy rather than to abnormalities of the fetus or neonate. For instance, maternal smoking during pregnancy increases the risk of several complications of pregnancy that may contribute to perinatal mortality, including abruptio placentae, placenta previa, bleeding early or late in pregnancy, and premature and prolonged rupture of membranes. The risk of preterm delivery, another complication of pregnancy, is also significantly greater in women who smoke while pregnant, even though their mean gestation is only one to two days shorter. As mentioned above, smoking during pregnancy increases the risk of sudden infant death syndrome, although the relative contributions of prenatal and postpartum maternal smoking to this effect are unknown.

Long-Term Growth and Development

A number of large, well-controlled studies provide evidence that the children of mothers who smoke during pregnancy have slight but measurable deficiencies in long-term growth and development, in terms of physical, intellectual, emotional and behavioral indices. For example, a longitudinal follow-up of 17,000 births, an estimated 98 percent of all births in England, Scotland, and Wales during the week of March 3-9, 1958, showed a dose-response relationship between maternal smoking during pregnancy and physical and mental problems of the children at seven and 11 years of age.[28] Controlling for the many potential confounding variables in such studies (e.g., the effects of post-partum maternal smoking) is difficult;

hence, more studies are needed to confirm these findings.

The Fire Hazards of Smoking in Hospitals

Besides the health hazards of involuntary smoking in the hospital setting, smoking also presents a significant fire hazard to hospitals. According to the Joint Commission on Accreditation of Hospitals (JCAH), smoking is by far the leading cause of hospital fires. The Commission estimated in 1980 that smoking is responsible for 60 percent of the 1500 annual *reported* hospital fires, while the next leading cause, faulty electrical wiring, caused 20 percent of such fires.[29]

The fire hazards of smoking in hospitals often receive more attention than the health effects of involuntary smoking on patients. Indeed, the JCAH accreditation standards for hospital guidelines on smoking[30] are almost entirely designed to reduce the fire risk:

> "*Smoking.* Because smoking has been acknowledged to be both a fire and health hazard,* a continuous effort shall be made to reduce its presence in the hospital. Written regulations governing smoking shall be adopted, and shall be conspicuously posted and made known to all hospital personnel, patients, and the public. These regulations shall include at least the following provisions:
>
> - Smoking shall be prohibited in any area of the hospital where flammable liquids or gases, or oxygen, are in use or stored. These areas shall be identified with "No Smoking" signs. When indicated, the signs shall be multilingual or shall make use of symbols.
> - Ambulatory patients shall not be permitted to smoke in bed.
> - Patients who are confined to bed should be discouraged from smoking.
> - Unsupervised smoking by patients classified as not mentally or physically responsible for their actions shall be prohibited. This includes patients so affected by medications.
> - Wastebaskets shall be made of noncombustible materials and shall not be used as ashtrays. Ashtrays shall be noncombustible.
> - Smoking shall be prohibited in areas where combustible supplies or materials are stored.
> - Smoking by personnel using the surgical and obstetrical suites shall be limited to dressing rooms and lounges; doors leading to the suites shall be kept closed."**

The only other references to smoking in the JCAH accreditation standards deal with the annoyance caused by involuntary smoking rather than its effects on patient's health. According to the section on "Rights and Responsibilities of Patients," "The patient has the right, within the law, to personal and informational privacy, as manifested by the right to ... request a transfer to another room if another patient or visitors in that room are unreasonably *disturbing* him by smoking or other actions" (emphasis added). Significantly, the nonsmoker is the one who must change rooms rather than the smoker, implicitly giving more weight to the "right" of patients or visitors to smoke than the right of patients to breathe clean air.

Public Attitudes on Restricting Smoking in Public Places

The U.S. Department of Health, Education, and Welfare (HEW) now the Department of Health and Human Services, (HHS), conducted a series of surveys on cigarette smoking during the past two decades.[31-33] Responses to the following statement show that a growing majority favor protection from involuntary smoking:

> "The smoking of cigarettes should be allowed in fewer places than it is now."*

	1964	*1966*	*1970*	*1975*
Agree	51.2%	51.8%	56.8%	70.1%
Disagree	38.8%	36.8%	36.3%	26.4%

The huge increase between 1970 and 1975 in the percentage of those who agree with the above statement is even more impressive given that smoking restrictions in public places were considerably more widespread in 1975 than in 1970.[34] By 1975, even a majority of smokers (51.1%) favored further limitations on smoking in public places.

The tobacco industry commissioned a similar survey by the Roper Organization in 1978.[35] It broke down the question by location, and found majority approval for segregating smokers and nonsmokers in every public place tested. The figures ranged from 91 percent for trains, airplanes, and buses, to 53 percent for barber and beauty shops. Although health care facilities were not included in this question, a related question showed that 69 percent of respondents were in favor of an outright ban on smoking in doctors' and dentists' offices and waiting rooms.

A third survey dealt specifically with smoking restrictions in health care facilities and restaurants. On the basis of 3313 field interviews, Barr and Lambert[36] found that 65.7 percent favored a total ban on smoking or separate areas for smokers and nonsmokers in these areas. Respondents generally supported greater restrictions (e.g., a total ban) in health care facilities than in restaurants. Even 52.4 percent of smokers indicated a preference for a total ban or separate areas for smokers.

Public opinion in favor of restrictions on smoking in public places is probably based on a combination of annoyance from exposure to sidestream smoke, and concern regarding the potential health hazards of involuntary smoking. The HEW surveys showed that a growing majority consider exposure to sidestream smoke to be annoying:

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*The term "health hazard" here probably refers to the effects on the smoker rather than on the nonsmoker.

**Although this provision could be based on the health hazards of involuntary smoking, the context implies that it is related to the fire hazards of smoking in areas where flammable (e.g., anesthetic gases are used.)

*For simplicity, responses are given as "agree" or "disagree." The original tables break down responses by degree of intensity (strongly agree, mildly agree, no opinion/don't know, mildly disagree, strongly disagree), by sex, and by smoking history (current smoker, former smoker, or "never" smoker). The figures cited above were derived by averaging the figures for males and females.

"It is annoying to be near a person who is smoking."*

	1964	*1966*	*1970*	*1975*
Agree	44.8%	47.9%	58.5%	62.5%
Disagree	51.7%	48.6%	38.3%	35.0%

In 1975, even 34.8 percent of smokers reported being annoyed by others' tobacco smoke (compared to 76.6 percent of nonsmokers).

Shephard and associates investigated this annoyance on the basis of location. They found that the percentage of nonsmokers annoyed by the accumulation of cigarette smoke varied from 72.2 percent for restaurants to 28.6 percent for shops. Medical facilities fell in the middle, with 41.8 percent of nonsmokers reporting annoyance therein. [3]

Interestingly, 66.7 percent of a sample of 483 smokers perceived that the accumulation of cigarette smoke would be more annoying to those in medical facilities than in any other location tested[3]

The Roper survey investigated respondents' perceptions of the dangers of involuntary smoking. A growing majority of the public believes that involuntary smoking is a health hazard, probably another major factor contributing to public opinion in favor of smoking restrictions:

"Is smoking hazardous to the nonsmoker's health?

	1974	*1976*	*1978*
Probably is hazardous	46%	52%	58%
Probably doesn't have any real effect	48%	40%	33%
Don't know/No Answer	6%	8%	9%

Why would a majority of smokers like to see tighter restrictions on smoking in public places; in effect, more limitations on their own behavior? First, some (especially light smokers) may be bothered by the concentrated smoke that often accumulates in public places, as suggested by their response to the statement regarding annoyance.[3] Second, others may respect nonsmokers' wish to be free from the annoyance and potential danger of secondhand smoke. Third, smokers who would like to reduce or quit smoking** may favor restrictions as a means to facilitate this end.

AMA Actions on Smoking

As early as 1953, the AMA Board of Trustees banned tobacco-product advertising from its publications. In 1962, the Board expressed additional concern about the health hazards of smoking and encouraged research in this area. In 1968, the AMA House of Delegates adopted a resolution calling for physicians to be nonsmoking exemplars and advisors, and for the AMA to discourage smoking with public pronouncements and educational programs. The same resolution directed the AMA to "take a strong stand against smoking by every means at its command," a position which the House of Delegates subsequently reaffirmed on five separate occasions. An amendment was added in 1969, calling for the AMA to point out to Congress the incongruity of spending tax dollars for production and sale of tobacco as well as for anti-smoking programs.

The AMA Education and Research Foundation (AMA-ERF) coordinated ten years of research on tobacco and health, the results of which were summarized and published by the AMA in 1978. The volume, "Tobacco and Health," explains the AMA-ERF research program and details the work of 844 researchers in 85 U.S. and foreign research institutions. A total of 795 papers on the relationship between smoking and disease were produced by the $15 million contributed by six tobacco companies.

Council on Scientific Affairs Report C (A-79), "Smoking and Health," reviewed the AMA's early role in anti-smoking activities, as well as current activities of the AMA and other health organizations. The final section of the report made a series of recommendations to Congress, federal agencies, insurance companies, schools, physicians, national, state, and local medical societies, and to the AMA itself.[37]

Since the adoption of Report C (A-79), the House of Delegates has approved policy calling for aggressive action to educate the general public on the hazards of cigarette smoking, emphasizing the high costs of this serious but preventable problem. Report EE (9A-81) of the Board of Trustees noted that "the AMA Division of Legislative Activities monitors congressional bills dealing with cigarette smoking and takes appropriate action." Consistent with this the AMA has supported the concept of a "cigarette safety act" that would require the manufacture and marketing of "fire-safe" cigarettes. Recently, the AMA supported the Comprehensive Smoking Prevention Education Act of 1983 (H.R. 1824), which would require:

1. a rotational warning system on cigarette packages and advertisements;
2. disclosure of tar, nicotine, and carbon monoxide levels on packages and advertisements; and
3. disclosure of the identity of cigarette additives to the Secretary of the Department of Health and Human Services.

The AMA has submitted statements to Congress on both proposed bills.

In June 1981, the AMA supported the elimination of the federal price support program for tobacco, (Resolution 132:A-81) and wrote to the publishers of the 200 leading newspapers and magazines in the country urging them to refuse to accept tobacco-product advertisements (Resolution 1:I-81). In June 1982, the House of Delegates voted to support continuation of a federal office on smoking and health. In December of the same year, the House agreed to "disapprove and discourage the promotional distribution of free cigarettes and to develop model state and local legislation to prohibit the practice on public property." In June 1983, the House called for the AMA to "work toward promoting a smoke-free society by the year 2000."

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*See foot note on page 301.

**According to the 1975 HEW survey, 60 percent of smokers have made at least one "fairly serious attempt" to quit smoking. Another 18 percent say that they would try to quit if only there were an easy way to do so, nine percent say "probably" or "it depends," and only nine percent say "no," they would not try. So overall, about nine out of ten smokers have either tried to quit smoking or would probably do so if there were an easy way available.[29] Approximately one in three adult smokers now say they have made "a fairly serious attempt" to quit smoking *during the* past year. [25]

Restricting Smoking in Public Places

Aside from these actions, the AMA has long-standing policy in favor of restricting smoking in public places. As early as June 1970, the AMA urged the Federal Aviation Administration to require separate sections for smokers and nonsmokers on commercial aircraft. In December 1979, the House of Delegates adopted Board of Trustees Report J, which advised the Civil Aeronautics Board (CAB) to strengthen its smoking regulations to include, among other things:

1. a ban on cigar and pipe smoking on all commercial aircraft; and
2. a ban on cigarette smoking on all scheduled flights of one hour or less and on all small planes of fewer than 60 passengers.

In April 1981, the AMA submitted a statement to the CAB supporting maintenance of the current airplane smoking regulations or, in the alternative, a complete prohibition of smoking on all commercial aircraft.

In June 1972, the House of Delegates voted to discourage smoking during all of its sessions. In June 1976, the AMA transmitted to state medical societies copies of Minnesota's statute that imposes strict regulations on smoking in public places. Two years later, in December, the AMA agreed to join, when requested by constituent societies, to support state legislation or public referenda to protect nonsmokers from tobacco smoke pollution in public areas and private areas open to the general public. Included in Council on Scientific Affairs Report C (A-79) were recommendations calling for the AMA to urge physicians to place "no smoking" signs in their offices and waiting rooms, to discourage smoking in the hospitals where they work, and to encourage smokers to recognize and be sensitive to the needs of nonsmokers. Report C (A-79) mentioned the finding of a recent Louis H. Harris poll that physicians' advice *coupled with prohibition of smoking at work and in public places* has a powerful impact upon the smoker's attitude toward the habit. The report also recommended that smoking by students and teachers not be permitted in elementary through senior high school, and that the AMA develop model legislation against smoking in public places.

With respect to smoking limitations in health care facilities, the House of Delegates voted in June 1978 to "encourage the elimination of cigarette sales and smoking in medical and health care facilities such as hospitals, clinics, medical schools, and nursing homes." The AMA model bill to restrict smoking in public places defines "public place" to include hospitals and nursing homes.

Hospital Policies on Nonsmoking

A 1979 survey of 360 randomly selected hospitals throughout the United States[38] indicated that hospitals were not demonstrating leadership in creating safe, nonsmoking environments for the patient, nor in offering non-smoking education programs to the community. This conclusion was drawn from the 91.7 percent return on questionnaires from administrative heads.

Only 1.2 percent of the hospitals surveyed totally banned smoking, and 56 percent continued to sell cigarettes on the premises. Eleven percent of hospitals even sold cigarettes from a cart circulating to patients' rooms. Only 46 percent asked patients prior to or on admission whether they preferred smoking or nonsmoking rooms. Visitors, patients who smoked, and physicians were seen by hospital administrators as the most resistant to smoking restrictions. The attitude and behavior of the hospital administrator appeared to have an effect on the smoking policies of the institution.

While 90 percent of the hospitals prohibited smoking in intensive and coronary care units, smoking was prohibited in only 64 percent of labor and delivery areas, 50 percent of pediatric areas, and 24 percent of wards. Smoking was allowed completely in the cafeterias, waiting rooms, and lobbies of 60 percent, 69 percent and 70 percent of the hospitals respectively.

A 1981 survey of 1168 community hospitals conducted by the American Hospital Association (AHA)[39] produced an 86 percent response. Ninety-one percent of the hospitals had a written policy on smoking and 97 percent restricted smoking to designated areas. Hospitals with 200 or more beds more often reported having written policies than those with fewer than 200 beds. As expected, hospitals within tobacco-growing regions had the lowest percentage of smoking policies.

Seventy percent of the hospitals do not sell cigarettes within the institution. It is significant to note that 90 percent of the hospitals having written policies restricting smoking do not sell cigarettes within the institution. *At the patients' request,* 86 percent of the hospitals will assign them to a nonsmoking room *when possible.* Smoking prevention programs are offered to patients hospitalized with illnesses related to cigarette smoking by 43 percent of the hospitals. Twenty-five percent of the hospitals offer stop-smoking classes for employees, and 17 percent provide patient education smoking classes. While 58 percent of hospitals indicated that the board of directors discussed the issue of smoking, such action was not a determinant in whether or not a hospital had a smoking policy.

Articles have been published regarding the successful implementation by individual hospitals of strict limitations on smoking on the premises. Louis A. Weiss Memorial Hospital in Chicago has established non-smoking floors, and its smoking policy is well publicized in prominently displayed signs, in a safety brochure given to all patients, in the hospital's manual on policies and procedures, and on visitors' passes.[40] New England Deaconess Hospital in Boston has adopted policy to make "no smoking" the rule throughout most of the hospital. Patients require their physician's written permission to smoke, smoking by staff and employees is restricted to departmental lounges and one cafeteria section; and visitors can smoke only in one area of the lobby.

The AHA study concluded that some of the obstacles to hospitals' efforts to control smoking are:

- Concern for the individual rights of smokers;
- Cost of implementing policies and programs;
- Economic status of tobacco producing states;
- Attitudes and smoking behavior of hospital staff and physicians;
- Difficulty of enforcing restrictions;
- Lack of governmental regulations to support restrictions;
- Time necessary to implement policies and programs; and
- Loss of revenue to the hospital gift shop.

To make further progress in the control or elimination of smoking within the hospital setting, management must recognize and address the obstacles cited above.

Conclusion

A growing body of evidence indicates that involuntary smoking may pose a health hazard to the general population. Certain groups of patients who often find themselves in hospitals (e.g., those with chronic cardiovascular or pulmonary disease) are especially susceptible to the ill effects of secondhand tobacco smoke. Cigarette smoking is by far the leading cause of hospital fires. The consequences of both involuntary smoking and fires in the hospital are more serious because of the physical incapacity and psychological debilitation of many patients.

A large majority of the public (including a majority of smokers) are in favor of restricting smoking in public places, including health care facilities. Current AMA policy supports more stringent limitations on smoking in public places, particularly health care facilities. In spite of public and AMA support for restricting smoking in hospitals, many still lack forceful policies in this regard.

Recommendations

The Council on Scientific Affairs recommends that the AMA encourage hospitals and physicians to support the following guidelines with respect to smoking in hospitals:

1. Physicians should take a leadership role in promoting the development of nonsmoking policies and programs within the hospitals.
2. Smoking should be prohibited in areas where oxygen or flammable materials are stored or in use.
3. Smoking should be prohibited in all corridors, elevators, and acute care areas.
4. Bedridden patients should not be permitted to smoke.
5. Smoking on patient floors by visitors, hospital staff, and ambulatory patients should be restricted to specifically designated, well-ventilated areas equipped to meet fire standards.
6. If smoking is permitted in cafeterias, other dining areas, employee lounges, waiting areas, and library facilities, it should have separate sections for smokers and nonsmokers. Where segregation is not feasible, smoking should be prohibited.
7. Smoking should be prohibited in all hospital staff meetings, Board meetings, and conferences (e.g., Grand Rounds).
8. Hospitals should ask all patients prior to or upon admission about their preference for a smoke-free room and guarantee that preference.
9. Hospitals should seriously consider designating one or more entire floors as completely nonsmoking.
10. No tobacco products should be sold in hospitals or on hospital grounds.
11. Signs should be posted at entrances to the hospital and in all nonsmoking areas to inform patients, staff, and visitors where smoking is prohibited. When indicated, the signs should be multilingual or should make use of symbols.
12. Hospitals should develop, implement, enforce and maintain a formal written smoking policy, to be distributed to all staff, visitors, and patients.
13. Either directly or in conjunction with other community agencies, hospitals should make available smoking education and cessation programs, literature, and other materials to patients, employees and the community.
14. Hospitals that restrict or eliminate smoking within the institution should initiate discussions with their fire and casualty insurance carriers consider reductions in insurance premiums.
15. Hospital administrators must be aware of *all* of the hazards of smoking and take the necessary steps to reduce these hazards. Administrators should utilize appropriate nonsmoking resource materials (e.g., those of the American Hospital Association) in developing policies on nonsmoking.

The Council also recommends that the AMA support revisions in the JCAH hospital accreditation standards pertaining to smoking in order to reflect the health effects of involuntary smoking as well as the fire hazards of voluntary smoking.

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BEHIND THE FACE OF HYPERTENSION

New evidence for central control

An Inside Look at the Health Policy Agenda

STEWART J. PETRIE, M.D.

When doctors get together to discuss the matter of "Where are we going in Medicine?," the most often heard statement is "Why doesn't organized medicine have an overall set of policies that we could address our activities and efforts toward, and thus not be in the position of reacting to somebody else's policies which may seriously affect our activities."

The Health Policy Agenda (HPA) project was conceived by the AMA Board of Trustees in early 1982 as a long-term approach to health care issues. The HPA is a broad-based outline of major health concerns—a plan for responding to social, economic, scientific, educational and political questions as they evolve. Once completed, the HPA will be the basis for a national agenda on health.

HPA involves practicing physicians, nurses, dentists, hospitals, third party payers, state and federal government, medical specialty societies, resident physicians, medical schools and students, pharmacists, osteopaths, business, labor and other health care groups. The two phases of the HPA project will take about three years to complete. Cost to the AMA, the sponsoring organization, will be $3.5 million for the life of the project.

The reasons that I am happy to be associated with this Health Policy Agenda (HPA) is that we are doing something which has a long range value and long range measurable good effects on the health status of our nation. Many of you will be happy to know that this is not simply a self-serving project but as later noted, it deals with the philosophy of medical care including such issues as ethical issues, education in medicine, its relationship to disadvantaged groups as well as evaluation of what has actually been promoted in the past and by present programs. Those in attendance included not only physicians but members from many other areas (such as nursing, pharmacy, and other health professionals). This is not proposed as a static document to reflect only present needs but a true living philosophy that will be able to change and thus afford continued medical health improvement for the decades ahead. I would like to take this opportunity to tell you how this works and my experiences thus far with this Health Policy Agenda.

As a member of the Advisory Committee, I met for the first time with my similar numbers for a very hot weekend in late August 1983. We were furnished in advance with the excellent work done previously by the work groups. (Dr. Frank Abbott, of our State Medical Society, is a member of one of these work groups). This was a two-day meeting, the first day being devoted to hearing committees (at which time testimony was given by the many registrants). The second day being devoted to the plenary sessions at which time the work of these hearing committees was condensed and given final debate.

From here, this information will be passed on to the Steering Committee. Approximately 280 people participated in the Advisory Committee meeting in Chicago, August 29th and 30th 1983. Of the 152 organizations invited to appoint a representative to this Advisory Committee, 129 sent at least one representative. Of the 280 registrants, 200 were Advisory Committee members, 64 were work group representatives and 16 were Steering Committee members. Forty of the 44 state medical societies, who have appointed members to this Advisory Committee, attended, and 12 states sent additional alternates. Of the 61 national medical specialist societies which had participated on the Advisory Committee, 53 sent representatives. Of the 33 health related organizations, 29 were represented at the meeting. Agenda books were also mailed to executive directors of all organizations participating on the Advisory Committee.

The way that this process was carried out is as follows: one was free to attend whichever of the hearing committees she/he wished. I was able to attend a good bit of the hearing committee on Medical Science, also those on Delivery Mechanisms and to a lesser degree, those on Education and Health Resources. In any case, at the plenary session of the following day, any further auditing of the deliberations could easily be attained and comments made at the plenary session. I was extremely impressed by the expertise and quality of the members present that gave testimony at the hearing committees. The hearing committees themselves were composed of two Steering

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STEWART J. PETRIE, M.D., Chairman, Department of Obstetrics and Gynecology, Griffin Hospital, Derby; CSMS Delegate to the AMA.

Committee members, work group chairmen and work group representatives. The hearing committee adopted the policy that a principle that was given would be discussed not only as to its *rationale* but to its *implications.* There was a statement of issues and background information on each of these principles. These principles listed were far reaching but time and space do not allow listing of all 148 principles. Nonetheless, examples of some of these principles dealt with such wide ranging areas as the discussions of the viability of our nation's biomedical research efforts (what part should be public and what part should be federal, etc), the private industries' contributions, and pharmaceutical research controls. Other principles dealt with care and safety of laboratory animals as well as the timely application by industry of new discoveries and knowledge to health care, etc. Other principles dealt with the appropriate roles of government and organized medicine in health care. In particular, a long time was spent with the forthcoming problems of medical care for our rapidly aging population.

Those interested in health education would have been very encouraged by many of the principles and discussions held under this hearing committee. Health manpower and delivery mechanisms and processes are areas that we are all now deeply concerned with and were discussed in great detail at these hearings with important policy statements therefore coming out of the plenary sessions. How will DRG's and cost containment measures affect quality of care?

The plenary session showed great agreement by the participants as a whole to those matters discussed upon the previous day at the hearing committees and with the work groups preliminary work. Several participants raised issues which affect the project as a whole rather than one individual work group. These issues included the necessity for a glossary; necessity to address overlaps and contradictions amongst the principles; importance of voluntary health organizations; the difficulty of examining principles divorced from policy implications; the need to address the "luxury" in some health care; the importance of securing labor participation in the project.

While many of us envisioned a lengthy day at the plenary session, the work was so well done by the work groups and hearing committees that wide acceptance was met with at the day of the plenary sessions and therefore the conclusions were rapidly reached. Thus the first meeting of this advisory committee ended even earlier than expected. I believe most of us left with a sense of having completed the first step in a very valuable contribution to all areas of health in our country.

As noted previously, the "flow sheet" in the case of final approval of the principles rests with the Steering Committee, which will then release them to participating organizations. This starts the second phase of the process, the identification of major health issues plus specific policy proposals to address them. It is expected that the HPA will serve as a model for health care planning of these organizations as well as a vehicle for policy accommodations with other organizations. A recent excellent article in the "AMA Auxillary" booklet called *Facets* concludes with a statement that "no private organization has even undertaken such a task. Certainly the AMA is to be commended for this positive step toward a systematic philosophy of health care delivery for all of us."

I want to make it clear that this is no idle debating club that talked to itself in only a self-serving manner. The committee has received wide ranging reports and from many diverse backgrounds and opinions in putting together this Health Policy Agenda. Even the choice of wording for this project was debated at great length before the term "Health Policy Agenda" was decided upon. Words that were discarded included "priorities," "health policy," "health plan" and other wording which implied that this was strictly a medically oriented, firmly entrenched program passed "from the top down." The present terminology of "Health Policy Agenda" seems to correctly imply the input of a consortium of affected peoples with an ongoing relationship and devotion to appropriate changes in such agenda.

It was a distinct pleasure for me to be there to represent our part of the country and to bring to the attention, at a national level, matters of concern to us regarding the many principles which were mentioned before and were thus addressed at this meeting. I have appended a list of these topics which appear under the six major headings that the HPA deals with. I have done this for three reasons. Firstly, I think that our membership would be interested in the previously mentioned wide range of topics under these six major headings that the HPA deals with. Secondly, if any members have an interest in a particular principle or point of view that they would like me to bring forth at these advisory committee meetings, they could contact me regarding presenting such information at a hearing committee. (We will be meeting again very soon.) Thirdly, I would like membership to know that I felt interested in so many of these principles that I wished I could have divided myself in several parts and attended many sessions at the same time. At a time when many of us may feel some discouragement over the proper role of medicine in our medical-political climate, it was heartening to be in close association with so many who spoke so well toward the designated principles. We have seen all too much of esoteric medical planning which has given short shrift to the clinicians and others dealing closely with patient care. Many times, I am asked, "What is the AMA's opinion on this and so." With the aid of this Health Policy Agenda, we should have an opinion which will go beyond what the AMA's opinion is and will include the best thinking of the many health professionals of our country as to what seems to be the best road to follow in the care of patients.

APPENDIX

HEALTH POLICY AGENDA FOR THE AMERICAN PEOPLE

REFERENCE LIST OF TOPICS

WORK GROUP 1—MEDICAL SCIENCE

Commitment to Medical Science
Freedom of Scientific Inquiry
Development and Evaluation of Health Care Technology
Communication in Medical Science
Ethics in Biomedical Research

WORK GROUP 2—EDUCATION FOR THE HEALTH PROFESSIONS

Access to Education for the Health Professions
Content and Administration of Programs of Education for the Health Profession
Financing Education for the Health Professions
Graduate Education for the Health Professions
Continuing Professional Education
Accreditation of Programs of Education for the Health Professions

WORK GROUP 3—HEALTH RESOURCES

Health Manpower
Health Care Facilities
Health Care Technology

WORK GROUP 4—DELIVERY MECHANISMS/PROCESSES

General Principles
Health Promotion and Disease Prevention
First Contact/Continuing, Referral/Consultation and Specialized Care
Long Term Care

WORK GROUP 5—EVALUATION, ASSESSMENT AND CONTROL

Professional Jurisdiction
Licensure
Professional Liability
Certification
Informing Patients
Peer Review
Confidentiality
Professional Judgment
Professional Standards and Government Regulation
Ethics

WORK GROUP 6—PAYMENT FOR SERVICE

Determination of Payment and Expenditures
Cost-Effective Health Care
Individual Choice of Provider
Payment for Terminal Care
Payment for Long Term Care
Education and Research

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A Thirty-Year Perspective of Anesthesia

AARON BOBROW, M.D.

I sit before my anesthesia machine, truly an imposing apparatus, and marvel at the progress in mechanical aids anesthesia has made. Not only do I have at my disposal a constant supply of nitrous oxide, oxygen and compressed air, but also vaporizers for halothane, enflurane and isoflurane. At hand is a mechanical ventilator to relieve me of "squeezing" the bag, along with a respirometer to guide me in delivering a specific tidal and minute volume. Of course, I can regulate the number of breaths per minute as well as the ratio of inspiration and expiration time. Specific fail-safe installations, including an oxygen analyzer and an audible alarm for every conceivable miscue, protect my patient. Blood pressures are recorded mechanically with a digital readout by my Infrasonde, as often as I desire it. My cardioscope is essentially interference free and I have a memory and a writer to document the patient's every deviation from the norm. Channels are available also to record arterial, central venous and Swan Ganz patterns and pressures. The patient's temperature is likewise monitored and my Doppler warns me of a possible air embolization. I can attach my carbon dioxide analyzer to keep track of that parameter. Once having adjusted my controls, I am the pilot, free to make judgments to regulate the depth of anesthesia and to record the anesthetic procedure.

As I contemplate all these marvels, I do get a bit nostalgic as my mind turns back to my earliest days in anesthesia, some thirty years ago, when like the airplane pilots of old, we flew, so to speak, by the seat of our pants, since these mechanical aids were not available.

How well I remember my earliest introduction to the world of sleep production for surgery at the Hartford Hospital, under Ralph Tovell. One of the early greats of modern anesthesia, Ralph preached the importance of our being well-grounded in pharmacology and respiratory physiology. He was a purist and insisted that his residents learn each anesthetic agent as an entity in itself, the better to understand its effects on the patient.

It is no wonder then that I started with drop ether. Learning the stages and planes of anesthesia was important and the patient had to be carried in the appropriate plane for the contemplated surgery. My armamentarium at first consisted of a can of ether, a wire mesh mask with layers of gauze, and oral and pharyngeal airways. Induction of the patient into the anesthetic state was correspondingly neither rapid nor pleasant. Needless to say, I was quick to learn with what repugnance and even violence necessitating forcible restraint ether anesthesia could be met. Since this was the agent of choice for tonsillectomies which then were frequently on the schedule, I had to learn the "art" of induction. When I was allowed to use vinethene ether for induction, the task became easier and swifter. No longer do we see the ether hook and foot pump with which we delivered the anesthetic for tonsillectomies. People look askance when I mention this device, which has long since disappeared.

I think back to the days when we overpowered our pediatric patients with ether and wonder what terrible psychic trauma we inflicted, and compare our present day approach. Now the child life specialist precedes us and prepares the child for the forthcoming "pleasant" experience. Premedication adequate to the situation is administered. The entire approach is kinder and gentler. That is not to say that we did not try our best years ago. How often did I tell childrens' stories while I started my anesthetic. Loud noises and conversations were forbidden in the operating room during induction and a careful slow approach to the patient prevailed. With the newer agents, of course, the entire process is smoother and more rapid. A bonus, of course, resulted from the fact that I no longer brought home the halo of ether that used to accompany me.

Airway management was a subject of prime concern and emphasis was placed on proper chin holding and the use of nasal and oropharyngeal airways. From drop ether, I graduated to the use of the anesthesia machine, the mask and the bag. Assisted and controlled ventilation were stressed and the "educated hand" had to learn to deliver a specific tidal volume. The physiology of respiration was constantly emphasized. Mechanical ven-

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tilators were not available, nor were arterial blood gases done to guide us.

The anesthetic quality of nitrous oxide and in combination with ether anesthesia was a standard approach. Proper delivery could yield good surgical relaxation and this was an almost foolproof modality. In the meantime, my senior resident was introducing me to the technique of endotracheal intubation. These days, when surgical patients are almost routinely intubated for even relatively minor procedures, it seems strange to contemplate that intubation at that time was considered a major intervention. The literature had frequent references to the complications of intubation and detailed specific indications and contra-indications for this procedure. Granulomas, chronic hoarseness, and vocal cord injuries were described as resulting from intubation. Surgeons were alert to the literature and were loathe to permit it as an elective device. Then, too, since curare was the only available relaxant, the delay in reaching a proper depth of anesthesia prior to intubation irked the usually impatient surgeon.

Reversal agents were imperfectly understood and the use of curare could result in a guessing game as the end of surgery approached, since the relaxant effects were not reversed but allowed to wear off. Although dosages were truly minimal as compared to today, timing to allow the relaxant to wear off was important lest respiratory assistance in the recovery room was to be continued.

Pentothal as an induction agent was of course a boon to both patient and anesthesiologist. Used as a drip along with nitrous oxide and curare, it furnished a pleasant approach. With the addition of morphine and demerol, it was the forerunner of our present day narcotic nitrous relaxant technique.

Cyclopropane, however, was considered the complete anesthetic and quickly became everyone's agent of choice. Along with moderate doses of curare, the patient could be carried in a light plane of anesthesia. A "touch" of ether was usually used to overcome the occasional arrhythmias we encountered. "Cyclo," being an explosive agent, called for specific precautions. Great care was taken to ground oneself via the Horton Intercoupler to the anesthesia machine, the patient and the operating table. The floors had to be conductive and our shoes likewise. Only cottons might be worn in the operating room.

We were not always as careful as might be, but were jolted back to reality when we learned that one of our confreres in a nearby hospital had suffered multiple lacerations as a result of a "cylo" explosion. His patient, though severely injured, fortunately recovered. Shortly thereafter, we had a seminar about the hazards of explosive or flammable anesthetics.

Succinylcholine was released to us in 1953 and crash intubations soon became the rule. The advent of the "sux" drip was popular with our surgeons who frequently asked us to speed up the relaxant drip rate. Needless to say, we did not always comply, but somehow relaxation seemed more complete to the surgeon if we nodded assent.

Work schedules for the resident were a bit different than those of today. Every other night was call night, and the following day we were still expected to work. Nonetheless, we survived and, indeed, had opportunities for fun despite the very busy operating room schedules.

Monitoring of patients consisted of a blood pressure cuff, a finger on the pulse, and observation of the patient's color and eye signs. Routine cardioscopic monitoring did not come into play until the early seventies. Even today, this is not always done. Constant alertness was the watchword and it paid off for me and my patient one day when I suddenly noted an extreme tachycardia. I notified the surgeon and, indeed, within a few more seconds, the pulse disappeared and I could no longer obtain a blood pressure. Immediately, the surgeon opened the chest and found the heart fibrillating. With cardiac massage, the heart reverted to normal rhythm, the blood pressure reappeared, and the surgeon was able to complete his procedure. Fortunately, the patient made a complete recovery. The diagnosis had been made without a cardioscope. External cardiac compression became the rule many years later as did also a clearer understanding of cardiopulmonary resuscitation.

In fact, the anesthesia department owned only one cardioscope. This was a massive instrument mounted on an unwieldy base. My senior project was to observe and record on an attached writer possible arrhythmias during intubation and anesthesia with this instrument. The delay in calibrating the "scope" and attaching electrodes to all four limbs brought me many complaints from the surgeons who could not see the necessity for all the "fuss." Indeed, we are presently a far cry from those days with our preoperative chest x-rays, EKG's and blood tests, as well as our present day monitoring. Our concern with a preoperative evaluation and preparation of the patient contrasts greatly with the rather cavalier approach of yesteryear. Then, the approach was largely in the hands of the surgeon who often insisted on his own premedication orders and even type of anesthesia.

With our ever broadening knowledge of the metabolism of anesthetic agents, the physiology of respiration, and dynamics of the cardiovascular system, the picture has changed. Anesthesiology has assumed its proper place in the care of the patient. With the advent of the non-explosive inhalation anesthetic agents—halothane, methoxyflurane, enflurane and now isoflurane, and with the exhaustive investigations that have been constantly carried on with regard to their effects on all aspects of the human system, patient care has been improved immeasurably. Potential complications resulting from these agents are well detailed so that a proper choice of anesthetic may be made. Relaxant agents and methods of reversal are much better understood. The narcotic nitrous relaxant technique so widely used now is a good example of the checks and balances we have at our disposal, since reversal of the effects of both the narcotic and the relaxant is available.

The days of the generalist are fading. Thus, we see more and more specialization emerging. Pediatric, neurosurgical, cardiac and regional anesthesiologists are sought. So too are specialists to care for chronic pain problems and experts in respiratory parameters. With our increasing understanding of the alpha and beta blockers, the usage of the nitrites and the calcium channel blockers, our armamentarium has advanced greatly. Now anesthesiologists are becoming more concerned with invasive procedures, developing their skills in inserting arterial lines, central venous lines, and Swan Ganz lines, all designed to assist in proper monitoring and carrying at-risk patients safely through the massive surgical procedures we encounter.

The anesthesiologist has truly arrived center stage. No longer is he confined to the operating room. His technical skills and consultative advice are sought in almost every area of medicine. Surely, it is both exciting and challenging to participate in a specialty which, though relatively young, has made such advances and holds forth so many new vistas for progress.

The nostalgia I feel is not for a return to the early days, but rather for the simplicity and warmth of old comrades in arms whose advice and encouragement were so valuable at times when the electronic and mechanical aids of today were unavailable. Worrying through a major procedure with a sick patient without the sophisticated tools we presently have was never easy. The diagnostic acumen and cooperation of old associates were frequently sought and freely given. What I most regret is the depersonalization that often comes with too many mechanical aids.

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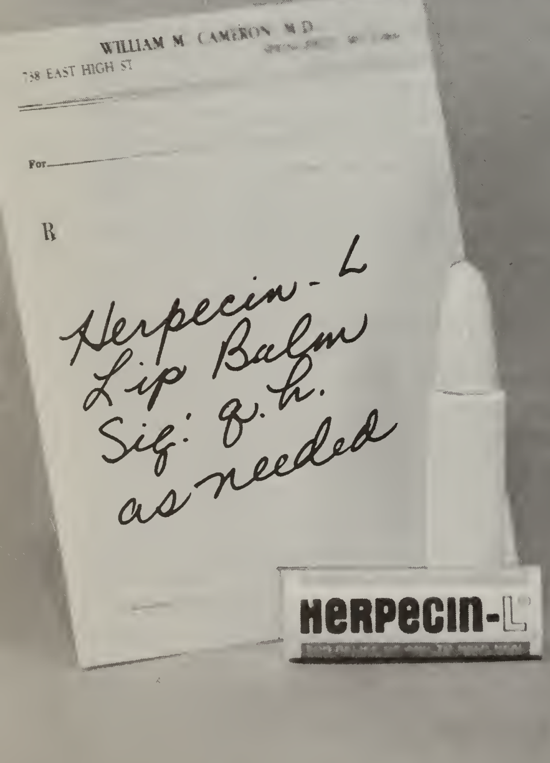

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Connecticut Right to Know Law

LEO UZYCH, J.D., M.P.H.

ABSTRACT–Connecticut law provides for the disclosure of information to affected employees, employers, and local fire marshalls about occupational toxins. A federal hazard communication promulgated in November, 1983 further provides for the disclosure of information about chemical hazards to workers in manufacturing. This article examines selected provisions of the state law of particular relevance to health professionals. A further purpose is to analyze the effect of the federal hazard communication on the state law. The state law would be relatively more protective of the public health if certain changes were made. The possible effect of the federal standard on the state law cannot presently be determined because of ongoing litigation. The medical community should become closely involved with evolving legislation in the right to know area so that the pertinent health-policy issues are decided in a humane and democratic manner.

Connecticut statutory law ("right to know" law) provides certain protections to employees possibly exposed to occupational carcinogens, reproductive hazards, and toxic substances.[1] Further legislative measures are needed to more fully protect workers as well as community residents from toxins emanating from the workplace. A hazard communication promulgated by the federal government in November, 1983 exerts an unknown effect on extant, as well as possible future, Connecticut right to know legislation.[2]

The Connecticut right to know law provides that employers using or producing carcinogens must post a list of all carcinogenic substances, in a manner readily available for viewing by employees.[1] New employees, during the first month of their employment, must be provided an educational and training program. This program must adequately describe the presence of occupational carcinogens, the dangers possibly associated with exposure to the pertinent substances, and proper methods for avoiding possibly harmful effects of such substances. All persons who supply carcinogenic substances to employers shall label all such substances by their generic or basic chemical name.

Upon offering employment to a prospective employee, each employer must similarly inform the prospective employee of any substances in the pertinent workplace which the employer should have reasonable cause to believe may cause birth defects or harm the reproductive system or a fetus. The employment, transfer, or promotion of an individual may not be conditioned on the sterilization of such person.

Connecticut statutory law further requires employers to provide information to employees about toxic substances. "Toxic substance" is defined statutorily as any substance which has been identified as an air contaminant under the specified Occupational Safety and Health Standards, Code of Federal Regulations, and which the employer uses or produces in the manufacture of any item, or which the employer uses or produces for purposes of research, experimentation or treatment. Each employer shall post a sign, at a location readily available for viewing by employees, informing employees of their right to information from their employer about workplace toxic substances. Each employee may request in writing from the employer statutorily-specified information, including the names of the toxic substances, the properties of the pertinent toxic substances, their acute and chronic effects, appropriate emergency treatment, and procedures for cleanup of leaks and spills involving such substances.

Persons who supply toxic substances to employers must also provide certain information to the employer. This information similarly includes the generic or basic chemical name of the pertinent toxic substances, their acute as well as chronic effects, symptoms of such effects, appropriate emergency treatment, proper conditions for safe use, and a label on each container stating that a toxic substance is contained therein.

On or before October 1, 1984, and annually thereafter, each employer who uses, keeps, stores, or produces any hazardous material in a manufacturing establishment must further provide certain information to the local fire marshall for the area in which the pertinent facility is located. "Hazardous material" is defined in the statute as any substance or material which has been identified by the Department of Transportation as a hazardous material in

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the pertinent parts of the Code of Federal Regulations, is present is quantities which exceed the maximum net quantity of the substance allowable for transport in one package by a cargo aircraft, as provided in the Code of Federal Regulations, and meets the definitional requirements of the hazard classes established for such hazardous materials in the Code of Federal Regulations. The fire marshall must specifically be notified in writing of the presence of hazardous materials in the pertinent manufacturing establishments, including information about the hazard class of each hazardous material and the location in the establishment where it can normally be found.

On November 25, 1983, the Department of Labor's Occupational Safety and Health Administration ("OSHA") promulgated a federal "hazard communication."[2] The hazard communication requires employers in the manufacturing sector to provide information to their employees about workplace toxins by means of hazard communication programs including labels, material safety data sheets, training, and access to written records. The federal hazard communication casts an uncertain effect on extant, as well as possible future, Connecticut legislation pertaining to right to know or chemical disclosure legislation. The federal rule is intended specifically to preempt any state law pertaining to communicating information about chemical hazards to employees in the manufacturing sector. State right to know legislation intended to protect the general public as well as workers outside of manufacturing should not be affected by the federal hazard communication. However, the federal hazard communication may preempt state legislation intended to protect workers in manufacturing.

The federal hazard communication is not fully effective until May, 1986. What will happen then is presently unclear. The possible preemption issues raised by state and local right to know legislation will probably be decided through litigation. A major lawsuit challenging the federal hazard communication has already been filed in federal court; on November 23, 1983, the Public Citizen Health Research Group, and others, filed a lawsuit in the United States Court of Appeals for the Third Circuit.[3] The lawsuit is claiming in part that the federal hazard communication is arbitrary and capricious because it fails to provide workers with adequate information about workplace hazards.

While legal challenges to the federal hazard communication are being litigated, careful legislative attention should be directed towards further provisions which may strengthen the Connecticut right to know law. The current state law does not specifically address the possible health dangers to community residents from workplace toxins. This is an important omission. The United States is an increasingly chemically-polluted society. About 1,000 new chemicals are marketed each year.[4] An estimated 40 to 50 million Americans may have been exposed at some point to one or more of the hazardous chemicals presently regulated by OSHA.[2] The quantity of hazardous waste produced each year in the United States is now estimated at between 150 to 275 million metric tons.[5] An estimated 90 percent or more of this waste is disposed of in a way that may threaten the public health. It is difficult to precisely determine the number of persons possibly harmed as the result of exposure to toxins emanating from the workplace. However, the Bureau of Labor Statistics reported about 168,000 new cases of occupational illness in 1976, and 162,000 in 1977.[4] These figures do not include workers who have left the workforce totally disabled from occupational illness associated with chemical exposures.

On the basis of the available, limited data, it is obvious that the attention of Connecticut legislators must be directed specifically to the problem of possible harm to community members associated with exposure to toxins emitted from the workplace. The legislative response of other states to this area may be of value in shaping possible future Connecticut legislation. A New York State Executive Order provides for the conducting of an industrial chemical survey, intended in part to inform citizens of any dangers posed by chemical dumps in their communities.[6] The New Jersey right to know law permits any person to request copies of environmental surveys and workplace surveys for industrial facilities.[7] A local Philadelphia Ordinance is intended to provide persons working or living in Philadelphia with information about toxic air contaminants which they may be exposed to, and possible resultant health harms.[8]

The extant Connecticut right to know law does not require that the local fire marshall be notified of the specific names of the pertinent hazardous materials.[1] This weakens the possible usefulness of the statute. Prompt, correct information about specific chemical identification may be of particular value to health care professionals treating persons exposed to occupational toxins.

The right to know area presents major issues with obvious possible impact on the public health. It is therefore very important for the members of the medical and public health communities to become knowledgeable in this area and closely involved with developing legislation, so that the pertinent health policy issues will be resolved in a humane and democratic matter.

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Month in Washington

Medicare Reform Movement Grows

Next year, Medicare spending for physicians services will "become the third largest federal domestic program—exceeded only by Social Security and the Medicare hospital insurance program," according to a study for the Senate Committee on Aging.

About one-third of all Medicare expenditures—nearly $25 billion—will go for physician care and spending on the supplemental medical insurance (SMI) side of the program is expected to increase by 16.1% in 1984. If the projection holds up, SMI will be the "fastest growing of the major domestic programs."

These statistics are likely to be cited again and again in the months and years ahead as Congress struggles to reduce the federal deficit, put Medicare's hospital fund back on sound financial footing, and determine whether the program's prospective hospital pricing system should be extended to physicians.

On March 16, they were the backdrop for discussion of a wide range of potential changes in Medicare physician reimbursement offered primarily by academicians and groups representing the elderly. Chaired by Sen. John Heinz (R-PA), the discussion centered primarily on suggestions that Medicare move to negotiated fee schedules or extend the hospital diagnosis related groups (DRGs) to physicians.

The only representative of organized medicine to testify at the hearing—AMA Board member James S. Todd, MD—reported that the AMA has asked physicians to voluntarily freeze fees for all patients. The New Jersey surgeon argued that a physician DRG system "would give substantial economic incentives to provide minimal care" and observed that current policies of the Federal Trade Commission appear to mitigate against the use of negotiated fee schedules.

The committee paper, written by former Office of Management and Budget health official Lyn Etheridge, contends that current Medicare reimbursement policies have "created unintended inequities among primary care physicians and specialists, inpatient and outpatient care, urban and rural areas."

In addition, Etheridge believes Medicare's current customary, prevailing and reasonable payment mechanisms has "distorted incentives for appropriate medical care" by encouraging hospitalization and surgery and the adoption of "add-on technology." He notes that the number of procedures that can be separately billed to Medicare has tripled since the program's inception and that the number of bills submitted by physicians increased by about 220% in the 1970s.

Since Medicare will constitute about 18% of the average physician's income in 1985 and since the physician supply in the United States has risen by 70% since Medicare's inception, Etheridge concludes that reform of Medicare's physician payment system is possible and might be accompanied by "improvements" in the claims assignment process.

One option examined by Etheridge was the use of negotiated fee schedules—an approach that is being tried in the Massachusetts Medicaid program and that was endorsed in the Social Security Advisory Council's recommendations for Medicare. The negotiated fee approach is also favored by Princeton economist Uwe Reinhardt, PhD, who told the committee that any "workable reform must be structured around the preservation of the fee-for-service approach."

A researcher with the University of North Carolina, however, said he thinks it will be "difficult if not impossible for the government to control physicians costs under the current fee-for-service reimbursement system." Thomas Rice cited his study of Denver physician reactions to a decline in Medicare reimbursement rates in 1977 as evidence that freezing physician reimbursement "is not effective" because physicians will "recoup lost income" by billing for "a greater number of services and for more highly-complex and costly" procedures.

In questioning, Sen. Heinz used Rice's predictions to suggest to Dr. Todd that the AMA, in addition to asking physicians to freeze fees, should recommend that volume be held to its current level. Todd "rejected the concept that physicians will raise the volume of services

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Prepared by the Washington, D.C.
Office of the American Medical Association

to get around a freeze" and pointed out that AMA policy already makes it "clearly unethical" to increase volume by providing unnecessary services. Todd said that increased volume could in fact occur for quite legitimate reasons—including an increase in elderly patients and improved technology.

Todd also noted that much of the increase in claims volume cited in the Etheridge paper may stem from a shift from inpatient to outpatient care that could save Medicare money. Furthermore, he reported, FTC and Justice Department actions involving relative value scales have stymied the use of RVS and fee schedules by physicians.

At the same hearing, representatives of the National Council of Senior Citizens and American Association of Retired Persons (AARP) called for mandatory assignment of physicians claims for inpatient services.

In 1980, aged beneficiaries' liability from unassigned claims exceeded $1.3 billion or about 13% of total physicians' charges for the elderly that year, AARP President-elect Vita Ostrander told the committee. Beneficiaries now pay over "60% of the cost of physician care of pocket," she added, and there is new evidence to show that some can no longer afford private insurance to supplement Medicare.

Ostrander added that "plans simply calling for participating physician agreements offer no assurance against a decline in the overall assignment acceptance rate." She called for adoption of a House proposal requiring the hospital to make affiliated physicians accept assignment.

AMA's Todd maintained that the current assignment option is "an important factor that has enabled physicians to treat Medicare patients in the same manner as other patients" because there is no difference "when it is time to submit bills for services."

Todd argued that much of the out-of-pocket costs Medicare beneficiaries face today are program copayments and insurance costs. He added that the bills that represent the greatest hardship for patients are also the most likely to be assigned.

Observing that a study by the Health Care Financing Administration has indicated that two-thirds of physicians, if confronted with an "all or nothing" system, would take no assignments, Todd opposed any major changes in the assignment option on grounds that it could "affect the access of Medicare patients to the physician of their choice." He called instead for "administrative modifications to the physician billing and payment process that could eliminate some of the paperwork "burden."

* * * *

Even More Mandatory Assignment Proposed

The most far-reaching proposal yet for requiring physicians to accept Medicare assignment was introduced in March by House Aging Committee Chairman Edward R. Roybal (D-CA) with the backing of two major organizations representing the elderly.

Roybal's proposal would require physicians who accept payment from Medicare to take all claims on assignment, thus prohibiting the physician from charging patients in excess of Medicare's fee allowances. As enforcement, the bill would require hospitals participating in Medicare to deny staff privileges to any physician who refused to sign agreements to assign all Medicare claims.

The bill, which was touted at a press conference alleging that physicians "overcharged" Medicare patients by $2.5 billion or $107 per Medicare patient last year, is backed by 11 senior citizens groups, including the American Association of Retired Persons and the National Council of Senior Citizens.

* * * *

New SHMOs Stalled By White House

White House budget office stalling on an experiment in financing long term care services has aroused the ire of some Congressmen and led to the introduction of legislation to put the project back on track.

Set up by Brandeis University, the experiment would combine health and social services under the auspices of groups called Social HMOs or SHMOs which would pool Medicare and Medicaid with private funds to pay for services.

Four SHMO sites had been selected and the project had received the blessing of private foundations that had donated about $4 million to the sites and of the Department of Health and Human Services which had agreed to participate in the demonstration.

The federal role was to come in the form of a waiver committing Medicare to pay the SHMOs more than will be available to other HMOs treating Medicare beneficiaries. While other HMOs, under regulations that still have not been published, are to receive 95% of the average cost of providing fee for service care to Medicare patients in the area, the SHMOs were to receive 100%. In return, they would provide social services and limited long term care coverage not provided by the typical HMO. Medicare was also to share in the financial risk of the SHMOs in their first two years.

Two years of negotiations has been completed and two sites—the Kaiser plan in Portland an ElderPlan in Brooklyn—were set to begin marketing in January. Brooklyn had hired staff and had a $60,000 monthly payroll to meet.

The other sites—a joint effort by the Ebenezer Society and Group Health in Minneapolis and the Senior Care Action Network (SCAN) in Long Beach, CA—were to begin marketing this spring or summer.

Then in late December, to the surprise of the Brandeis project officers, the White House of Management and Budget entered the picture. OMB officially has no say so over the Medicare waiver process but most approve the necessary forms to evaluate demonstrations and waivers. OMB has questioned other Medicare waivers, including those to states rate setting programs exempted from Medicare's diagnosis related groups (DRG) payment system. Brandeis staff say they believe their SHMO project got caught up in a general battle between OMB and HHS over where the final waiver authority lies.

At the end of March, the SHMO project was back at the Health Care Financing Administration which was responding to a detailed list of questions ranging from some of the department has dealt with before—what will happen to the Medicare beneficiaries at the conclusion of the demonstration?—to some very specific ones regarding the potential cost of the project.

The latter issue, according to HCFA staff, appears to be the sticking point. Recalling experience with the Medicare hospice benefit, the budgeteers are reluctant to test a politically-popular concept they fear Congress might expand to all Medicare beneficiaries before the demonstration of its cost implications is completed.

The SHMO concept has gained support among some important legislators, including Sen. David Durenberger (R-MN) who heads the Senate Finance health subcommittee. Durenberger, who has one of the SHMO sites in his state, was instrumental in adding a provision to the Senate Finance Committee's budget deficit package instructing HHS Secretary Margaret Heckler to go ahead with the SHMO demonstration.

* * * *

Organ Transplant Bills Move in Congress

Two organ transplant bills, both designed to ease organ procurement, worked their way through the House and Senate this March.

The more conservative bill, sponsored by Sen. Orrin Hatch (R-UT), would create a task force to review public and private efforts needed to set up an organ procurement system. The recommendations of the task force would not be mandated, but handed over to the President and two House and Senate committees for review.

It also permits the Department of Health and Human Services, if desired, to establish a national organ procurement and transplantation registry. Action is not required, explain supporters, because there is no consensus on the need for a federally-run procurement system.

The more radical bill, sponsored by Rep. Albert Gore (D-TN), would authorize grants to improve organ procurement, including participation in a new national transplantation network. It would also require HHS to set up a computerized national transplantation network to help match donors and recipients.

Most controversial, however, is a provision that gives HHS authority to ration the delivery of services to all Medicare recipients. Specifically, Title II of the House bill would allow the Secretary to determine for any "health care technology or procedure" paid for through the Medicare program, those Medicare beneficiaries who would be eligible for such services, those medical facilities in which the services can be provided, and the conditions under which the services would be provided.

While the Hatch bill has won the unanimous support of a Senate committee and seems headed for a warm reception on the Senate floor, the Gore bill faces a tougher fight in the House.

* * * *

Separate Department of Health Urged by AMA

Simply removing the Social Security Administration from the Department of Health and Human Services and setting it up as an independent agency will not "satisfactorily deal with the organizational problems" of HHS, James Davis, MD, told a panel studying such a move.

Dr. Davis, Vice Speaker of the AMA House of Delegates, testified before the congressional panel on Social Security organization. The panel was directed in the 1983 Social Security Amendments to do an implementation study for the establishment of an independent Social Security agency.

Dr. Davis recommended that the Health Care Financing Administration, which administers Medicare and Medicaid, not be transferred away from other health functions within the existing HHS and said that ideally, a separate department of health should be created with a physician as Secretary.

As a transition to a separate department of health, he suggested that "a position of Under Secretary of Health could be created to direct all of the health functions" of HHS.

* * * *

Congress Grapples with Capital Costs Under DRGs

Congressional efforts to hold down prices in Medicare's diagnosis related groups (DRGs) payment system will have far more impact on hospitals' access to the financial markets than any new policy specifically dealing with the treatment of capital under DRGs, hospital officials say.

Their comments came before a hearing of the Senate Finance health subcommittee which is gathering background before coming up with a specific proposal later this year for bringing capital into the DRG system. The law specifies that capital costs are to remain under cost reimbursement until October 1, 1986.

Sometime before October 1, 1984, the Department of Health and Human Services must develop a policy on the treatment of capital under DRGs. Various interest groups also are beginning to develop their own proposals which range from an across-the-board percentage DRG add-ons to continuation of all or part of the current cost-based method of paying for capital.

Medicare pays only a small portion of the total hospital capital cost in the United States but its policies influence hospitals' access to other capital markets. In addition, it is estimated that every dollar invested in capital generates 22 cents in additional operating expenses for the institution.

In fiscal, 1984, Medicare will pay inpatient capital-related costs of about $3 billion, HHS estimates. Capital expenditures will thus represent about 7.4% of Medicare payments for inpatient hospital operating costs.

Capital costs vary widely among hospitals, however, with about one-fourth having depreciation and interest costs less than 4% of operating costs while one-fifth have ratios between 10% and 20%. In general, hospitals with lower ratios of capital to operating costs include government-owned, teaching, and New England hospitals as well as those with heavy Medicaid loads. Those with higher capital to operating cost ratios include for-profits and those which have changed bed size in the last five years.

A number of factors influence a hospital's access to capital, hospital officials from the major hospital associations, told the Senators. They include "size and name recognition," medical staff composition, market penetration and the percentage of a hospital's patients who are Medicare and Medicaid beneficiaries. Since the bottom line is whether or not the hospital generates a surplus, Federation of American Hospitals Executive Director Michael Bromberg added, "decisions on ratcheting down on limiting DRG prices will have much more impact than anything we do on the capital side."

* * * *

Specialists' Hospital Contract Legal, Court Says.

An exclusive arrangement between a metropolitan hospital and a specialty group violates no anti-trust laws, the Supreme Court ruled in March in a case brought by a Louisiana anesthesiologist.

Although the arrangement may frustrate outside anesthesiologists and inconvenience surgeons, it does not restrain competition because other hospitals – without such an arrangement – are nearby, the justices agreed in a 9-0 decision.

East Jefferson General Hospital in Metairie, LA, has a contract with Roux and Associates to perform all anesthesiological services for its patients.

The arrangement was challenged by Edwin Hyde, MD, who was barred from admission to the hospital's staff. He charged the hospital with violation of the Sherman Anti-Trust Act.

In late 1982 an Appeals Court ruling found in Dr. Hyde's favor, saying that the arrangement was anti-competitive because patients in the hospital were "compelled" to use the hospital's anesthesiology services.

But the Supreme Court overturned the decision, finding that patients are not "compelled" to go to East Jefferson General Hospital; in fact, 70% of the patients residing in Jefferson Parrish enter one of the 20 other hospitals in the area.

* * * *

FDA Sets Stronger Labeling for Accutane

The FDA in March agreed to revised labeling for the Roche Laboratories' anti-acne drug Accutane. Birth defects and spontaneous abortions have occurred in association with the use of this drug and the new labeling strengthens the warnings that the drug should not be used in pregnant women. FDA is requiring Roche to advise all physicians of the new labeling which Roche says they are now doing. FDA also issued a warning that women should not take Accutane unless they are using some form of birth control.

A consensus development conference recommended to the FDA that they take a critical look at analgesic compounds because there is evidence that when taken in large doses over prolonged periods they cause serious kidney damage. The word from FDA, however, is that they aren't likely to take any action in the forseeable future.

* * * *

Heckler Launches Anti-Cancer Campaign

Department of Health and Human Services Secretary Margaret M. Heckler launched a new cancer prevention campaign in March, saying that an estimated 80% of cancer cases are linked to lifestyle and environmental factors. "Too few Americans realize the simple truth that cancer is caused by the way we live, and its risks can be reduced by the choices we make," she said. The public's perceptions about cancer have failed to keep pace with new medical knowledge, she explained.

Heckler's campaign represents a significant turnaround for federal policy. Less than five years ago, then-HEW Secretary Joseph A. Califano resigned in part due to lack of support for his anti-smoking crusade. The current Agriculture Secretary John R. Block once said that he didn't think the USDA should be telling consumers how to eat.

By the year 2000, the new campaign hopes to have saved 75,000 lives a year through reduced smoking and 20,000 lives a year through improved diet. An additional

105,000 lives are expected to be saved through improved use of cancer treatments.

An estimated 35% of all cancer deaths can be traced to low-fiber, high-fat diets; 30% to smoking; 3% to alcohol; 5% to virus; 4% to occupational exposure to toxics; 3% to excess sunlight; 2% to environmental pollution and 1% or less to food additives, Heckler said.

The $686,000 campaign will kick off in June, first with TV commercials and then with pamphlets for persons at high risk.

* * * *

HHS to Cut Its Staff

HHS Secretary Margaret Heckler, following up on the recommendations of the Grace Commission, plans to abolish 1,264 jobs in her office. Fifty-six positions would be abolished in the Office of the Assistant Secretary for Planning and Evaluation—a move that appears to give the White House Office of Policy Development a larger say in health policy.

* * * *

Senate Unit Trims Medicare, Medicaid

A month of haggling and horsetrading in the Senate Finance Committee produced a deficit-trimming package that includes about $10 billion in Medicare and Medicaid cuts over the next four years.

Premium increases for Medicare beneficiaries and physician fee limits were scaled down somewhat from earlier versions of the proposal. The changes appeared to come at the expense of hospitals.

Finance's $74 billion deficit downpayment over four years would raise $48 billion in revenues largely through tax changes and reduce spending by $26 billion.

The physician fee proposal would produce an anticipated four-year savings of $1.5 billion. It would freeze customary and prevailing fee limits for all physicians for one year beginning July 1, 1984. A freeze on prevailing fees only would continue for a second year for physicians who did not elect to become Medicare "participating" physicians agreeing to assign all claims.

Beneficiaries have been given some relief under the final propoal. A plan that would have gradually increased the Medicare Part B premium to 35% of Part B costs was replaced with a provision holding the Part B premium to 25% of costs.

The committee more than doubled its earlier cuts in Medicare payments to hospitals. In its final form, the Finance measure holds increases in the hospital specific portion of Medicare rates to the market basket increase minus ½%. The national and regional portion will be permitted to rise by the market basket plus ½%.

Other provisions would:

- Pay independent laboratories and physicians offices 60% and hospital labs 62% of prevailing charges for lab tests.
- Round payments for Part B claims down to the next lowest dollar.
- Require HHS to study the reasonableness of Part A payments for pacemaker implants and set up a pacemaker registry in the FDA.
- Require the establishment after July 1, 1984, of separate reimbursement limits for hospital-based and free-standing skilled nursing facilities. Limits would also vary according to whether the SNF was rural or urban.
- Disallow the reevaluation of hospital assets acquired in fiscal 1985 and thereafter, thereby limiting the amount of capital related costs a new owner can claim for Medicare reimbursement purposes.
- Provide money from the Medicare trust funds to keep professional standards review organizations (PSROs) operating until they are replaced by peer review organizations (PROs).
- Delay the date by which all hospitals must contract with a PRO and after which intermediary PROs are permitted.

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Government Wants Reconsideration on Baby Jane Doe Records

Rebuffed by a three-judge panel of the U.S. Court of Appeals, the Reagan Administration has asked for a full panel of judges to reconsider a recent Baby Jane Doe decision refusing to turn over hospital records to the government.

Should the Administration's request be rejected, the case may move on to the U.S. Supreme Court.

Meanwhile, the AMA and several other hospital and medical groups have independently filed suit against HHS Secretary Margaret Heckler to overturn the final Baby Doe regulations which went into effect in February. The suit was not brought in Washington, but in the U.S. District Court of New York where the Baby Jane case was originally filed.

* * * *

Hospital Mergers Studied

The major incentive in a recent trend toward hospital mergers and acquisitions is probably new tax advantages rather than the increased Medicare reimbursement for capital that occurs upon a change in ownership, Congressional Budget Office official told two House Ways and Means subcommittees recently.

Nevertheless, Nancy Gordon predicted, disallowing a reevaluation of capital costs and assets following ownership changes could save Medicare and Medicaid $830 million over the next five years.

The hearing stems from a General Accounting Office report alleging that reevaluation following the Hospital Corporation of America's acquisition of Hospital Affiliates International increased overall capital costs at the institutions by about $5.5 million, an unspecified portion of which was picked up by Medicare.

The Senate Finance Committee subsequently included in its budget deficit reduction package a provision disallowing reevaluation in acquisition and mergers after October 1, 1984. Ways and Means member Rep. Willis Gradison, Jr. (R-OH), plans to introduce similar legislation in the House.

* * * *

NIH Panel Warning on Analgesics

Taken separately, aspirin and acetaminophen can provide fast, safe pain relief. Taken together over-time, they can cause kidney disease and chronic renal failure, according to a National Institutes of Health conference panel held in March.

Patients should be warned about the dangers of sustained use of combinations of antipyretic analgesics. Furthermore, serious consideration should be given to withdrawing these combination drugs—over-the-counter remedies such as Anacin and Vanquish—from the market, they said.

Preparations containing a single analgesic agent do not appear similarly harmful, they said. Rather it is the combination of ingredients which appear to produce a unique almost synergistic, type of toxicity.

Researchers suspect an interaction between the two components. Acetaminophen causes tissue injury when it converts to toxic metabolites; however, these metabolites alone are rarely cause for concern. Aspirin or other salicylates enhance this toxicity, however, by lowering levels of the protective substance glutathione.

Acetaminophen and aspirin both tend to concentrate in the kidney's papilla. Because they also inhibit prostaglandin synthesis and reduce medullary blood flow, they may enhance papillary damage.

Problems appear to develop in patients who take about three kilograms of combination analgesics over a three-year period, or an average of 10 tablets a day for three years. The inclusion of stimulant drugs such as caffeine encourage long-term habitual use, the panel said.

* * * *

No Relief for DRGs

A provision that would have slowed the phase-in of Medicare's diagnosis-related groups pricing system died an early death in Congress in March when the House Ways and Means Committee abruptly set aside consideration of the measure that had been approved by its health subcommittee.

DRGs are to be phased in over three years in the initial phase, rates are to be based 75% on hospital specific rates and 25% on a federal rate. The subcommittee provision would have extended the period of time in which hospitals remained in this first phase.

The hospital industry was badly split over the issue, however, with for-profit and southern hospitals opposing the delay while the American Hospital Association and Catholic hospitals supported it.

A new move is afoot to permit a hospital to appeal to Medicare Provider Reimbursement Review Boards its designation as a rural or urban hospital, its area wage index or its census region assignment. The new effort appears to have support from all segments of the industry and may not be opposed by the Administration which had argued against the delay in the DRG phase-in.

* * * *

Heroin Again Considered for Cancer

The heroin controversy, quiet for the past three years, once again created a stir on Capitol Hill. This time, unlike before, legalization efforts have the support of more than 40 Congressmen and a variety of physicians.

A bill, introduced by Rep. Henry Waxman (D-CA) and cleared by his Energy and Commerce Subcommittee on Health in March, would establish a four-year program which would make heroin available to physicians through qualified pharmacies. It would require intravenous administration of the drug, and restrict use to cancer patients with intractable pain.

No one disputes that heroin is a very effective painkiller, yet even its supporters concede that heroin, if legal, would help only a handful of patients. It is not a wonder drug and should be used only to ease the pain of persons who can find relief no other way, they said.

In congressional hearings, legalization of heroin was strongly opposed by the American Medical Association and by Edward N. Brandt, MD, Assistant Secretary for Health of the Department of Health and Human Services. "There is no clinical evidence to support the thesis that heroin is needed to improve physicians' ability to manage severe, chronic pain," Dr. Brandt said.

AMA testimony was presented by Kathleen M. Foley, MD, Chief of Pain Service at Sloan-Kettering. Education, not legislation, is the key, she and Dr. Brandt told Congressmen. "The AMA believes that where cancer patients suffer needlessly, it is not due to a lack of effective analgesis medications, but because of ineffective use of such medications. The AMA is working to ensure that physicians are aware of the most effective pain management techniques presently available," she said.

The Subcommittee bill was significantly modified to reflect many of AMA's concerns and at month's end AMA staff and Committee staff were still discussing the package.

Inactivated Hepatitis B Virus Vaccine

CENTERS FOR DISEASE CONTROL

Introduction

Worldwide, recommendations for using hepatitis B virus (HBV) vaccine will vary in accordance with local patterns of HBV transmission. In the United States, an area of low HBV prevalence, certain groups are at substantially greater risk than the general population of acquiring infection. It is for these higher-risk groups that the vaccine is currently recommended. To date, 12,000 individuals have been given this vaccine, and no untoward effects have been observed over periods of time extending up to 3 years. The recommendations that follow are intended as initial guides for immunization practice, and will be modified as additional data and experience are accumulated. Because the cost of this vaccine is high, a discussion of the cost effectiveness of prevaccination susceptibility testing is included.

Hepatitis B Virus Infection in the United States

The estimated lifetime risk of HBV infection in the United States varies from almost 100% for the highest-risk groups to approximately 5% for the population as a whole. An estimated 200,000 persons, primarily young adults, are infected each year. One-quarter of them become ill with jaundice. More than 10,000 patients are hospitalized with hepatitis B each year, and an average of 250 die of fulminant disease. Between 6% and 10% of young adults with HBV infection become carriers. The United States currently contains an estimated pool of 400,000-800,000 infectious carriers. Chronic active hepatitis develops in over 25% of carriers (100,000-200,000), and often progresses to cirrhosis. Furthermore, recent studies have demonstrated an association between the HBV carrier state and the occurrence of liver cancer. It is estimated that 4,000 persons die from hepatitis B-related cirrhosis each year in this country, and that more than 800 die from hepatitis B-related liver cancer.

The role of the HBV carrier is basic to the epidemiology of HBV transmission. A carrier is defined as a person who is HBsAg positive on at least 2 occasions, at least 6 months apart. Although the degree of infectivity is best correlated with HBeAg positivity, any person with a positive test for HBsAg is potentially infectious. The likelihood of developing the carrier state varies inversely with the age at which infection occurs. During the perinatal period, HBV transmitted from HBeAg-positive mothers results in HBV carriage in up to 90% of infected infants, whereas 6%-10% of acutely infected adults become carriers.

Carriers and persons with acute cases have highest concentrations of HBV in the blood and serous fluids; less is present in other body fluids, such as saliva and semen. Transmission is via percutaneous or permucosal routes. Infective blood or body fluids can be introduced by means of contaminated needles or through sexual contact. Close personal contacts such as those that occur among household contacts of HBV carriers or among children in institutions for the mentally retarded can also spread infection. Transmission of infection by transfusion of contaminated blood or blood products has been greated reduced since the advent of routine screening with highly sensitive tests for HBsAg.

Although subtypes of HBV exist, infection or immunization with 1 subtype confers immunity to all subtypes.

Serologic surveys demonstrate that although HBV infection is uncommon among adults in the general population, it is highly prevalent in certain groups. Those at risk, based on the presence of serologic markers of infection, are described in Table 1. Immigrants/refugees and their descendants from areas of high HBV endemicity are at high risk of HBV infection. Homosexually active males and users of illicit injectable drugs are among the highest-risk groups, acquiring infection soon (10%-20%/year) after adopting these lifestyles. Inmates of prisons also appear to be at high risk, possibly as a consequence of drug abuse or homosexual practices. Patients and staff in custodial institutions for the mentally retarded are also at increased risk of have HBV infection. Classroom contacts of some deinstitutionalized carriers may also be at higher risk than the general population. Intimate household and sexual contact with HBV carriers increases risk, as does receiving certain pooled plasma products and undergoing hemodialysis.

Table 1

EXPECTED HEPATITIS B VIRUS PREVALENCE IN VARIOUS POPULATION GROUPS

	Prevalence of serologic markers of HBV infection	
	HBsAG(%)	*All markers(%)*
High risk		
Immigrants/refugees from areas of high HBV endemicity	13	70-85
Clients in institutions for the mentally retarded	10-20	35-80
Users of illicit parenteral drugs	7	60-80
Homosexually active males	6	35-80
Household contacts of HBV carriers	3-6	30-60
Patients of hemodialysis units	3-10	20-80
Intermediate risk		
Prisoners (male)	1-8	10-80
Staff of institutions for the mentally retarded	1	10-25
Health-care workers		
Frequent blood contact	1-2	15-30
Low risk		
Health-care workers		
No or infrequent blood contact	0.3	3-10
Healthy Adults (first-time volunteer blood donors)	0.3	3-5

There is increased risk for certain medical and dental workers, and related laboratory and support personnel, who have frequent contact with blood from infective patients. Employment in a hospital without exposure to blood carries no greater risk than that for the general population.

Vaccine

Hepatitis B virus vaccine is a suspension of inactivated, alum-adsorbed 22-nm surface antigen particles that have been purified from human plasma by a combination of biophysical (ultracentrifugation) and biochemical procedures. Inactivation is a 3-fold process using 8-M urea, pepsin at pH 2, and 1:4,000 formalin. Each of these processes has been shown to inactivate HBV and representative viruses from all known groups, and thus should inactivate any viruses potentially contaminating the vaccine. HBV vaccine contains 20 μg/ml of HBsAg protein.

After a series of 3 intramuscular doses of HBV vaccine, an average of over 90% of healthy adults developed protective antibody.[1,2] A course of 3 10-μg doses induces antibody in virtually all infants and children 3 months through 9 years of age tested to date. Protective antibody titers have persisted during 3 years of observation, although a gradually declining titer has been observed.

Field trials of the United States-manufactured vaccine have shown 80%-95% efficacy in preventing infection or hepatitis among susceptible persons.[3,4] Protection against illness was complete for persons who developed antibodies after vaccination but before exposure. The duration of protection and the consequent need for booster doses are not yet known.

Studies are planned or are under way in various settings to assess the value of vaccination after HBV exposure. For post-exposure prophylaxis, see the ACIP recommendations for the use of immune globulin;[5] see below for recommendations regarding infants born to mothers who are HBV carriers and for sexual contacts of patients with acute hepatitis B.

Vaccine Usage

Primary adult vaccination consists of 3 intramuscular doses of 1.0 ml of vaccine (20μg/1.0 ml) each. The second and third doses should be given 1 and 6 months, respectively, after the first. For patients undergoing hemodialysis, and for other immunosuppressed patients, 3 2-ml doses (40μg) should be used. For children under 10 years of age, 3 similarly spaced doses of 0.5 ml (10 μg) are sufficient. Vaccine doses administered at longer intervals than those stipulated provide equally satisfactory protection, but optimal protection is not conferred until after the third dose. Since HBV vaccine is an inactivated (non-infective) product, it is presumed that there will be no interference with other simultaneously administered vaccine(s). The duration of protection and the need for booster doses have not yet been determined.

Vaccine Storage

Vaccine should be stored at 2C-8C but not frozen. *Freezing destroys the potency of the vaccine.*

Side Effects and Adverse Reactions

Side effects among 12,000 recipients of HBV vaccine observed to date have been limited to soreness and redness at the injection site.[3,4]

Data are not available on the safety of the vaccine for the developing fetus, but because it contains only non-infectious HBsAg particles, the risk to the fetus from the vaccine should be negligible. In contrast, HBV infection in a pregnant woman may result in severe disease for the mother and chronic infection for the newborn. Pregnancy should not be considered a contraindication to the use of this vaccine for persons who are otherwise eligible.

Effect of Vaccination on Carriers

The vaccine produces neither therapeutic nor adverse effects in HBV carriers.[6]

Vaccination of Immune Persons

Vaccination of individuals who possess antibodies against HBV from a previous infection is not necessary but will not cause adverse effects. Such individuals will have a post-vaccination increase in their anti-HBs levels. Passively acquired antibody, whether from hepatitis B immune globulin (HBIG) administration or from the transplacental route, will not interfere with active immunization.[7]

Prevaccination Serologic Screening for Susceptibility

HBV carriers and those having antibody from previous infection need not be vaccinated, but serologic screening to detect such individuals before vaccination may or may not be cost effective. The decision to screen potential vaccine recipients is an economic one that depends on 3 variables: 1) the cost of vaccination, 2) the cost of testing for susceptibility, and 3) the prevalence of immune individuals in the group. All are important in estimating whether routine, selective, or no screening will be most economical in an HBV vaccination program.

Figure 1 shows the relative cost effectiveness of screening, given different costs of screening tests and the expected prevalence of immunity. In constructing the figure, the assumption was made that the cost of 3 doses of vaccine is $100 and that there are additional costs for administration. For any combination of screening costs and immunity to hepatitis, the cost effectiveness can be estimated. For example, if the expected prevalence of serologic markers for HBV is over 20%, screening is cost effective if costs of screening are no greater than $30/person. If the expected prevalence of markers is less than 8%, and if the costs of screening are greater than $10 per person, vaccination without screening is cost effective.

Screening in groups with the highest risk of HBV infection (e.g., users of illicit injectable drugs, homosexually active males, and institutionalized mentally retarded persons) will be cost effective unless testing costs are extremely high. For groups at intermediate risk (e.g., health-care workers with an expected prevalence of 8%-20%), cost effectiveness of screening may be marginal, and vaccination programs may or may not utilize screening. For groups with a low expected prevalence of HBV serologic markers (e.g., entering health professionals) screening will not be cost effective.

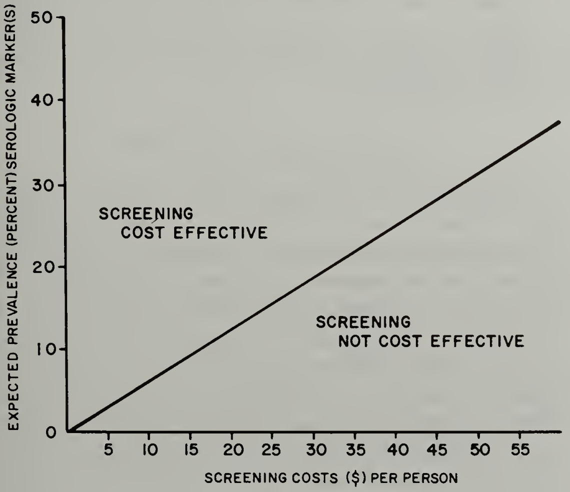

Figure 1
Cost effectiveness of pre-vaccination screening of hepatitis B virus vaccine candidates*

*See text for assumptions.

For routine screening, only 1 antibody test, either anti-HBc or anti-HBs, need be used. Anti-HBc will identify all previously infected persons, both carriers and those who are not carriers, but will not discriminate between members of the 2 groups. Anti-HBs will identify those previously infected except for carriers. For groups expected to have carrier rates of <2%, such as health-care workers, neither test has a particular advantage. For groups with higher carrier rates, anti-HBc may be preferred to avoid unnecessary vaccination of carriers. If a radioimmunoassay (RIA) anti-HBs test is used for screening, a minimum of 10 RIA sample ratio units should be used to designate immunity (2.1 is the usual designation of a positive test).[4]

Serologic Confirmation of Post-Vaccination Immunity

HBV vaccine produces protective antibody (anti-HBs) is more than 90% of healthy persons.[1,2] Revaccination of those persons who did not respond to the primary series has produced antibody in only one-third. Thus, there seems little need to test for immunity following vaccination except for dialysis patients, whose subsequent management depends on knowing their immune status.

Pre-Exposure Vaccination

Persons at substantial risk of HBV infection who are demonstrated or judged likely to be susceptible should be vaccinated. They include:

> *Health-care Workers*—Health-care workers (medical, dental, laboratory, and support groups) have varied risks of exposure to HBV depending on their jobs. Those workers for whom vaccine is recommended should be vaccinated as soon as possible after beginning work in a high-risk environment, ideally during their period of training.
>
> *Hospital Staff*—Hospital staff are at increased risk of HBV infection because of contact with blood and blood products. The risk for hospital personnel can vary both among hospitals and within hospitals. In developing specific immunization strategies, hospitals should use available published data about the risk of infection[8-10] and, in addition, may wish to evaluate their own clinical and institutional experience with hepatitis B.
>
> Studies in urban centers have indicated that occupational groups with frequent exposure to blood and/or needles have a substantial risk of acquiring HBV infection. The highest risk is for

individuals with frequent blood exposure, including the following groups: medical technologists, operating room staff, phlebotomists and intravenous therapy nurses, surgeons and pathologists, and oncology and dialysis unit staff. Other groups that have been shown to be at increased risk in some hospitals include: emergency room staff, nursing personnel, and physicians. To quantitate HBV risks among workers, groups can be ranked according to their frequency of blood/needle exposure. Additional information can be obtained from employee health records, serologic prevalence surveys, and estimates of HBsAg prevalence among patients.

Other Health-Care Workers—Other health workers, based outside of hospitals, who have frequent contact with blood or blood products are at increased risk of acquiring HBV infection. These include dental professionals (dentists, oral surgeons, dental hygienists), laboratory and blood bank technicians, dialysis center staff, morticians, and similar professionals.

Clients and Staff of Institutions for the Mentally Retarded—Susceptible clients and selected staff of institutions for the mentally retarded should be vaccinated. Risks for staff are comparable to those for health-care personnel in other high-risk environments. However, the risk in institutional environments is associated not only with blood exposure, but is also consequent to bites and contact with skin lesions, saliva, and other infective secretions.

Hemodialysis Patients—Numerous studies have established the high risk of HBV virus transmission in hemodialysis units. While recent data have shown a decrease in the rate of HBV infection in hemodialysis units following introduction of environmental control measures, vaccination is recommended for susceptible patients.

Homosexually Active Males—Susceptible homosexually active males should be vaccinated regardless of their age or duration of their homosexual practices. It is important to vaccinate persons as soon as possible after their homosexual activity begins. Homosexually active females do not appear to be at increased risk of sexually transmitted HBV infection.

Illicit Injectable Drug Users—All users of illicit injectable drugs who are susceptible to HBV should be vaccinated as early as possible after their drug use begins.

Recipients of Certain Blood Products—Although screening of all blood donors for HBsAg has decreased the incidence of transfusion-related HBV infection, patients with clotting disorders who receive factor VIII or IX concentrates have an elevated risk of HBV infection. Vaccination is recommended for these persons, and should be initiated at the time their specific clotting disorder is identified. Screening is recommended for patients who have already received multiple infusions of these products.

Household and Sexual Contacts of HBV Carriers—Household contacts of HBV carriers are at high risk of HBV infection. Sexual contacts appear to be at greatest risk. Vaccination of susceptible household contacts of carriers is recommended. At present, most carriers are identified through routine screening of donated blood, diagnostic testing in hospitals, or through other screening programs among high-risk groups. As part of expanded HBV control programs, additional screening to identify HBV carriers may be warranted.

Other Contacts of HBV Carriers—Persons in contact with carriers at schools, offices, etc., are at minimal risk of contracting HBV, and vaccine is not routinely recommended for them. However, classroom contacts of deinstitutionalized mentally retarded HBV carriers who behave aggressively or have special medical problems that increase the risk of exposure to their blood or serous secretions may be at risk. In such situations, vaccine may be offered to classroom contacts.

Special High-Risk Populations—Some American populations, such as Alaskan Eskimos, and immigrants and refugees from areas with highly endemic disease (particularly eastern Asia and sub-Saharan Africa) have high HBV infection rates and deserve special attention. Depending on specific epidemiologic and public health considerations, more extensive vaccination programs may be warranted.

Inmates of Long-Term Correctional Facilities—The prison environment may provide a favorable setting for the transmission of HBV because of the frequent use of illicit injectable drugs and homosexual practices. In such institutions, prison officials may elect to undertake screening and vaccination programs.

Post-Exposure Vaccination

Infants Born to HBsAg-Positive Mothers—Pregnant women who are HBsAg positive should be informed about the risk of transmission to their infants. Infants born to these women should receive HBIG.[5,11] Infants whose mothers are chronic carriers will be continuously exposed to HBV throughout their childhood; therefore these infants should receive vaccine. The optimum timing for vaccination in conjunction with HBIG administration has not been established. Pending additional information, it is recommended that vaccination begin at 3 months of age or shortly thereafter. Studies to determine the immunogenicity and efficacy of vaccine at birth, with or without HBIG, are currently under way.

Sexual and Household Contacts of Acute Hepatitis B Cases and Health Workers Who Receive Needle Sticks from HBsAg-Positive Patients—Possible alternatives for post-exposure prophylaxis include HBIG, immunoglobulin (IG), HBV vaccine, or a combination of vaccine and an immune globulin. Recommendations for immune globulin use have already been published.[5] Studies are currently under way to evaluate the use of vaccine in some of these settings. No recommendations can be made at this time for post-exposure use of HBV vaccine.

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DIAGNOSTIC AND THERAPEUTIC Technology Assessment (DATTA) released opinions on four procedures that are controversial in the medical community. The opinions represent the consensus of responses to questionnaires mailed to four separate panels. Each panel consists of no less that 40 physicians across specialties who either use a procedure or refer patients to those who do. The return rate exceeded 80%. The opinions will be published in the Journal of the AMA. The full opinions, and the 13 preceding ones, are available from Nancy Cahill, Director, Technology Assessment, AMA headquarters, Chicago, (312) 645-4530. In separate studies, the panels concluded that:

> Diaphanography (transillumination of the breasts) for cancer screening is to be considered investigational until adequately controlled comparisons with mammographic screening are reported.
>
> Implanted electrospinal stimulator for scoliosis is to be considered investigational until additional data confirms that it is as effective as the Milwaukee Brace.
>
> Treatment of childhood leukemia after a second or later relapse with total body irradiation and bone marrow transplantation is an established procedure in those patients not successfully controlled by chemotherapy.
>
> In the absence of controlled studies, no consensus could be reached about the safety and effectiveness of gastric bypass or gastroplasty in the management of morbid obesity.

—AMA *Newsletter,* Vol. 16, No. 8, 1984.

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Differences in Practice Characteristics Between Female and Male Physicians

AMA CENTER FOR HEALTH POLICY RESEARCH

The proportion of female physicians within the physician population is growing. From 1970 to 1981, the percentage of female physicians increased from 7.7 percent to 12.2 percent. Correspondingly, 16.3 percent of physicians under the age of 45 in 1981 were female compared with 7.7 percent of physicians over 45 years old. Female physicians are also relatively concentrated in certain specialty groups. In 1981 females comprised 8.9 percent of general/family practitioners and 5.6 percent of surgeons, in contrast to 15.4 percent of medical specialists and 15.1 percent of other specialists.

Past studies by Kehrer and Langwell (*Journal of Human Resources,* 1976 and 1982 respectively) have indicated that, in addition to differences in their age and specialty distributions, there are differences in the socioeconomic practice characteristics of male and female physicians. This report provides further information on the socioeconomic characteristics of male and female physicians. Specifically, the report:

- compares male and female physicians with respect to employment status, practice hours, patient visits, and earnings; and
- examines the degree to which differences in these characteristics may be accounted for by differences in age and specialty distributions.

The data used are from SMS surveys for the first through fourth quarters of 1983 and the AMA Eighth Periodic Survey of Physicians.

Differences in Employment Status, Practice Hours and Visits per Week

Female physicians were less likely to be self-employed and, on average, practiced fewer hours and had fewer patient visits per week than their male counterparts in 1983. As shown in Table 1, the share of female physicians who were self-employed was 26.4 percent smaller than among male physicians. Female physicians on average worked 7.9 percent fewer hours and saw 18.5 percent fewer patients per week than male physicians.

Table 1

DIFFERENCES IN EMPLOYMENT STATUS, PRACTICE HOURS, AND PATIENT VISITS BETWEEN FEMALE AND MALE PHYSICIANS, 1983

	Percent Difference Between Female and Male Physicians		
	Share Self-Employed	*Total Practice Hours Per Week*	*Total Visits Per Week*
ALL PHYSICIANS	−26.4%	−7.9%	−18.5%
Specialty			
General/Family Practice	−30.8	−14.1	−21.7
Medical Specialties	−25.6	−10.6	−18.9
Surgical Specialties	−13.5	0.7	−17.8
Other Specialties	−23.4	−6.9	−11.6
Age Group			
40 years or less	−28.4	−10.6	−20.1
40-55 years	−25.2	−6.6	−16.6
56 years or more	−21.7	−12.1	−17.3
Employment Status			
Self-Employed	–	−5.4	−21.1
Employee	–	−8.6	−4.3

The lower percentage of self-employed physicians among females may result in part from differences in the age distribution of male and female physicians. Among age groups, the differential in the likelihood of self-employment is largest for physicians 40 years of age or younger, and smallest for physicians over age of 55. This may be explained by the greater potential for career interruptions among younger female physicians (e.g., for child bearing and rearing). Since career interruptions are likely to be more costly for self-employed physicians because of the foregone returns to the investment in developing a practice, younger females may prefer to practice medicine as employees to avoid these costs.

For the most part, differences in hours and visits are not attributable to differences in specialty and age

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SMS Report, March 1984, Vol. 3, No. 2. Reprinted with the permission of The AMA Center for Health Policy Research.

The AMA Center for Health Policy Research directs the Socioeconomic Monitoring System in cooperation with the AMA Division of Survey and Data Resources.

Table 2

AVERAGE ANNUAL NET INCOME AND INCOME PER HOUR AFTER EXPENSES BEFORE TAXES BY SEX AND SPECIALTY, 1972 AND 1982

	Net Income ($1000)			*Income Per Hour ($)*		
	1972	*1982*	*Average Annual Percent Change*	*1972*	*1982*	*Average Annual Percent Change*
ALL PHYSICIANS						
Male	47.9	102.0	7.9%	21.9	39.8	6.2%
Female	27.6	65.2	9.0	15.6	30.1	6.8
Specialty						
General/Family Practice						
Male	41.6	72.8	7.0	18.6	27.1	3.8
Female	22.3	50.5	8.5	13.0	22.0	5.4
Medical Specialties						
Male	43.9	86.3	7.0	19.4	32.0	5.1
Female	23.5	48.8	7.6	13.3	22.2	5.3
Surgical Specialties						
Male	55.8	126.1	8.5	25.4	49.2	6.8
Female	35.2	92.4	10.1	18.7	38.8	7.6
Other Specialties						
Male	47.5	109.0	8.7	22.7	44.5	7.0
Female	28.9	74.5	9.9	16.7	35.8	7.9
Age Groups						
40 years or less						
Male	43.2	93.6	8.0	19.6	37.1	6.6
Female	24.3	60.2	9.5	14.4	31.8	8.2
40-55 years						
Male	53.3	115.8	8.1	22.5	45.5	7.3
Female	32.8	73.2	8.4	17.5	32.7	6.5
56 years or more						
Male	42.8	89.8	7.7	22.7	38.9	5.5
Female	21.8	69.5	12.3	13.3	39.1	11.4

Source: 1983 SMS Core Survey and the 8th Periodic Survey of Physicians.

The SMS surveys for 1st through 4th quarters of 1983 contain a representative sample of 7,630 non-federal patient care physicians and achieved a pooled response rate of 63.0 percent.

distributions. Indeed, in many cases the differences between female and male physicians are larger for physicians within similar specialty and age groups. Among surgeons, however, there was no significant difference in hours worked between females and males. The difference in total visits was smaller for employee physicians than for self-employed physicians.

Earnings Differences Between Female and Male Physicians

Female physicians, on average, earn less from medical practice than male physicians. As indicated in Table 2, the average net income (income after expenses but before taxes) of male physicians in 1982 was $102,000, compared to $65,200 for female physicians. Part of this income differential is attributable to differences between female and male physicians in hours practiced, specialty, age, and employment status. For example, as noted previously, females tend to work fewer hours than males. Thus, adjusting income for hours of practice reduces the magnitude of the earnings differential. The difference in average net income per hour of practice between male and female physicians in 1982 was 24 percent, compared to the 36 percent difference in average net income before adjusting for hours of practice.

The differential also narrows in most cases if the average net income per hour of practice for female and male physicians within the same specialty are considered. For example, in 1982 females in general/family practice earned 19 percent less per hour of practice than their male counterparts. Similarly, females in medical specialties earned 31 percent less, females in surgical specialties earned 21 percent less, and females in other specialties earned 20 percent less than males in the same specialty classification.

At least part of the remaining differential results from differences in the age distribution of female and male physicians. Indeed, among physicians over the age of 55, female physicians on average earned more per hour than males in 1982. On the other hand, female physicians 40 years of age or younger earned 14 percent less, and female physicians 41-55 years old earned 28 percent less, than males in the same age group.

Since self-employed physicians have higher average earnings than employee physicians, the earnings differential may also reflect differences in employment status between male and female physicians. Results not shown in Table 2 indicate that in 1982 among self-employed physicians, females earned 18 percent less per hour than males. Among employee physicians, females earned 21 percent less per hour than males. Both of these earnings differentials are smaller than the 24 percent differential in earnings per hour before adjusting for employment status.

Differences in earnings between male and female physicians that remain after accounting for differences in hours of practice, specialty, age and employment status may result from a variety of factors, such as differences in case-mixes and board certification status. As noted by Langwell in an earlier study, some patients may also prefer to be treated by male physicians. This would tend to reduce patient visits for female physicians, and in turn reduce earnings. However, earnings differentials do not appear to result from differences in productivity, at least as indicated by the average length of an office visit (30.5 minutes for females and 31.6 minutes for males).

Finally, to determine whether the gap in earnings between male and female physicians has increased or decreased over time, differences in rates of growth in net practice income and net income per hour are examined. For female physicians, net income increased from $27,600 in 1972 to $65,200 in 1982—an average annual rate of increase of 9.0 percent. For male physicians, the average annual rate of increase in net income was 7.9 percent over the same period. In terms of income per hour, the average annual rate of growth from 1972 to 1982 was 6.8 percent for female physicians and 6.2 percent for male physicians. Moreover, the rates of growth in both net income and net income per hour are higher for females than males within all four specialty classifications and two of three age groups. Thus, the earnings differential between male and female physicians appears to be closing slowly over time.

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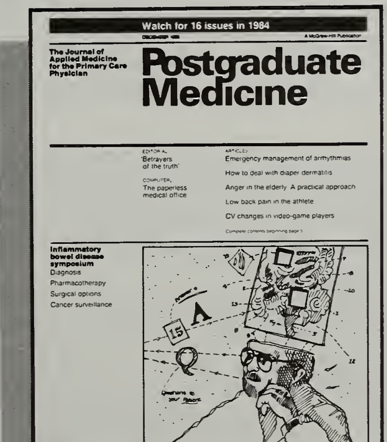
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The President's Page

Unfinished Business

In one of my first editorials I pledged to initiate a more equitable distribution of AMA delegates according to geographic distribution of membership, and to encourage wider participation by the limitation of tenure. This was brought about in part by the allocation of additional delegates and alternates to Connecticut to serve a growing AMA membership. I have held firm to the belief that an effective organization can only be achieved by shaping our representative body to most closely mirror our membership. In order to achieve this goal, we must allow for a reasonable turnover of leadership and for the distribution of our representatives in accordance with the one man, one vote principle.

Those delegates currently in office have not been enamoured of this suggestion. Nevertheless, I requested passage of a resolution to distribute delegates according to geographic distribution of members. This was promptly voted down at the Council.

At a subsequent meeting, I moved to establish an ad-hoc committee to study the problem and come up with recommendations to the Council. This time the resolution was approved. The committee, comprised of Lawrence B. Ahrens of New Britain, Chairman, W. Raymond James of Essex, Stewart J. Petrie of Derby, Walter B. Reyelt, Jr. of Sharon, and John J. Sullivan, Jr. of Stamford, submitted the following recommendations to the Council:

1. That the nominating committee and preliminary selection committee shall be directed to make every effort to select one delegate and one alternate delegate from each of the large counties of Fairfield, New Haven and Hartford, and one delegate and one alternate delegate from any of the five smaller counties in the state.
2. That tenure shall be limited to eight years of continuous service which may be repeated after an interval of no less than one year.
3. That no delegate or alternate delegate be nominated at any age beyond 69.
4. That alternate delegates be given priority consideration for the position of delegate whenever possible.

After much debate, recommendations one and four were passed by the Council while recommendations two and three were defeated. The Council, it appeared, had taken the first step to reaffirm to the general membership the fact that the Connecticut State Medical Society is indeed an organization truly representative of the physicians of the state of Connecticut.

If Connecticut is to distinguish itself on a national level, our currently-serving delegates must be willing to sacrifice their tenure to the long term goal of adequate, equitable and proportional representation.

This being my last President's Page, I wish to express my appreciation of having had the privilege and honor of serving the Society, and I hope that my efforts have had a positive impact on our future directions.

Daniel W. Doctor, M.D.
President

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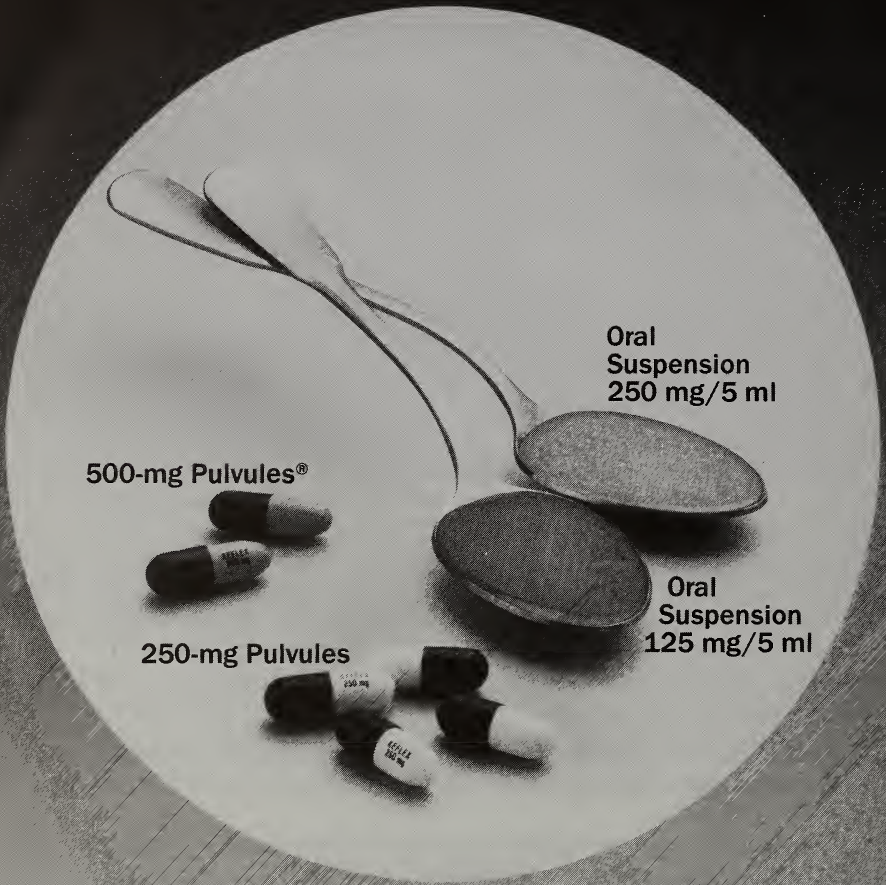

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Reflections from the Dean's Office

Honest Work

ROBERT U. MASSEY, M.D.

At a recent meeting of medical school deans, one of the discussion topics was "Ethical issues in a competitive or prospective pricing reimbursement system." Later the deans devoted a half day to a consideration of their schools' most important task, "Educating students in the clinical disciplines and in the basic science disciplines." The matter of ethics carried over from the first discussion to the .second.

The formal processes of moral reasoning, of weighing the patient's interests and society's concerns in the dilemmas presented by today's half-way technologies, did not seem to be quite the same as conforming to a standard of conduct or of right behavior, implied by the definitions in the dictionary for both *ethical* and *moral.* Reasoning it out might be something anyone with a modest intellectual endowment could learn to accomplish; even a well-programmed computer could, with the proper input, produce the best possible moral conclusion; give expensive treatment in this case, withhold it in that. There are frequently too many dimensions to allow any of us to rely on hunches, or even upon what we hope is sound clinical or moral judgment.

And would the computer be delivering an ethical judgment, an economic conclusion, a political opinion, or just the best clinical judgment?

When the deans began to talk of clinical education, a new idea emerged, this time simpler: morality is inherent in the craft. Said another way, the good craftsman makes morally sound decisions "conforming to a standard of right behavior" for the sake of his work. The detective story writer, Dorothy Sayers, expressed something like this when she wrote:

"No piety in the worker will compensate for work that is not true to itself; for any work that is untrue to its own technique is a living lie."[1] She proposed that "the worker's first duty is to *serve the work* (italics hers):"

> "—the moment you think of serving other people, you begin to have a notion that other people owe you something for your pains; you begin to think that you have a claim on the community. You will begin to bargain for reward, to angle for applause, and to harbour a grievance if you are not appreciated. But if your mind is set upon serving the work, then you know you have nothing to look for; the only reward the *work* can give you is the satisfaction of beholding its perfection. The work takes all and gives nothing but itself; and to serve the work is a labour of pure love."

I believe that Dorothy Sayers meant that to apply to our work as clinicians, scientists, and teachers, as well as to painting and cabinet making, and to her own work as the creator of Lord Peter Wimsey: the morality is in the craft; it is one with the craftsmanship.

The deans' discussion of clinical education began with their affirmation that medicine is first of all a craft or an art, and although it has been served, not always well, by philosophy in the past, and is well served by science today, it remains what Hippocrates called it in his first aphorism: *techne.*

Whether insistence upon good *techne* makes a moral craftsman, or whether only the moral craftsman can produce good *techne* is too much of a chicken and egg problem to be resolved easily. But clinical teachers know there is an invariable connection; the clinician recognized as great by his peers, his students, and his patients would probably have difficutly distinguishing his moral from his clinical judgment, or either from his work.

In *The Two Cultures,* C.P. Snow has an idea about science very like Dorothy Sayers' idea about work; speaking of scientists, he wrote:

> "In the moral, they are by and large the soundest group of intellectuals we have; there is a moral component right in the grain of science itself—."

Perhaps it is because science is so unforgiving; errors, even honest errors, will finally be found out. But that is so with clinical work as well, and here, as with other kinds of craftsmanship, the work well done has integrity: it has wholeness, uprightness, and honesty.

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ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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Editorials

Why Not Ban Smoking in Health Care Facilities

We will not bore you with statistics of what you already know about smoking and health. We commend all of you who have quit, but we feel personal quitting is no longer enough. It's time for action. Health professionals must become involved and initiate efforts to help in the smoking fight.

Walk around your hospital or health care facility. Look closely at where smoking is allowed. Look again, this time to see what is actually happening. Do you see people smoking in areas where cancer patients are being cared for? Where chemotherapy or radiation therapy is being given? Is there smoking on medical floors? In offices? Is smoking allowed in the obstetrics and gynecology departments? Is there smoking where there are cardiac patients? When the door opens from a conference room, does a patient see nurses coming out of a smoke-filled room?

In a recent study of smoking habits amoung nurses in Connecticut, we found many nurses had stopped (only 25.5% of the nurses report smoking, down from 39.8% in 1975).[1] Yet to our dismay, we discovered that a majority of nurses who continue to smoke stated they smoked more at work and did so in lounges, conference rooms, offices and cafeterias. On the other hand, a majority (78%) agreed that nurses should not smoke while on hospital duty, although there was less agreement on the subject from nurses who smoked. The practice of smoking at work by nurses has been confirmed by another study, with force of habit reported as the major reason.[2]

Are you aware of the Connecticut Clean Indoor Air Act? Passed in 1983, smoking is prohibited in health care facilities in any diagnostic or treatment area and in waiting rooms in those areas. In other areas, smoking is permitted only where a sign is posted so indicating. (Health care institutions are defined as hospitals, nursing homes, rest homes, homes for the aged, home care agencies and infirmaries of schools, municipalities and corporations. Only doctors' offices are not included).

Many hospitals have already been successful in implementing strict limits on smoking. The Medical Board at Yale-New Haven Hospital has recently approved a policy of "no smoking" in patient rooms. The New England Deaconess Hospital in Boston has a "no smoking" rule throughout most of the hospital. Patients need their doctors' *written* permission to smoke, smoking by staff and employees is restricted to departmental lounges and one cafeteria section, and visitors can smoke only in one area of the lobby.[3] At the clinical center at National Institute of Health, there is no smoking in offices or in patient units. The Louis A. Weiss Memorial Hospital in Chicago has nonsmoking floors and a 1979 survey of 360 randomly selected hospitals throughout the U.S. indicated that 43 of them totally banned smoking.[4]

Corporate America has also instituted non-smoking policies. In March, the toughest anti-smoking law in the country went into effect in San Francisco, giving nonsmokers in offices and factories the power to decide whether and where there can be smoking on the job. In Connecticut, the Meriden Record-Journal, a morning newspaper with 160 full-time workers, recently joined other firms in banning smoking in all work areas. The State Department of Health, under Commissioner Douglas Lloyd, has banned smoking in all its own work areas.

The public is ready for action on banning smoking, particularly in medical facilities. A 1978 study by the tobacco industry reported that 69% of respondents were in favor of an outright ban on smoking in doctors' and dentists' offices and waiting rooms.[5] Barr and Lambert reported from 3313 field interviews that 65% favored

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Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

separate areas for smokers and non-smokers or a total ban in health care facilities and restaurants.[6]

It is no longer enough for health professionals to personally kick the habit. Nor is it enough to stop selling cigarettes and to designate non-smoking areas in our health institutions. It's time for us—the Connecticut health professionals—to set an example and ban smoking in health care facilities. Every single one of us needs to take on the task personally in our own work areas. We have to start asking questions about why smoking is being allowed and what we can do to change the policy.

We think it's a case of where one person can make a difference. Won't you try?

M.K. Tish Knobf, RN, MS
Clinical Nurse Specialist Oncology
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Know the Rules of Reporting

The average reader who suddenly finds himself the subject of a news story can find the press a mysterious and confusing institution with which to deal.

People willingly talk with reporters, but sometimes shudder when they see what they have said in print, especially when their names are used. Some try to wiggle out of the problem by claiming they were misquoted or their remarks taken out of context. Others, though, are genuinely confused by the process and didn't expect to see their comments published.

Public officials and those in public relations who often talk with the media learn the rules quickly and generally are able to live with them, although they, too, sometimes complain about the system.

The simplest and most important thing to remember is that unless a specific agreement is reached beforehand, everything said to a reporter may be used in the newspaper. Except in unusual circumstances, a reporter calls or stops by not because he wants to be sociable, but because he is gathering information. Not all news sources feel free to tell everything they know for publication. Some are willing to talk as long as we don't identify them; others want to give us information purely on a confidential basis; others will only give us hints as to where the information can be found.

To help reporters and news sources understand what information is fair game and what isn't, a complicated set of rules and definitions has evolved over the years. Even among some journalists, there is disagreement as to what each definition means precisely. Here are some generally accepted definitions in use at The Courant:

On the Record. All information and the name of the news source may be used in the story. All interviews are conducted on the record unless an agreement is reached to the contrary. In most cases, reporters won't say an interview is on the record; the assumption is that if you talk to a reporter you are talking for the record.

Not for Attribution. This is information given to a reporter that may be published, but the identity of the source may not be used. Example: A prosecuting attorney tells a reporter he will move for a mistrial in a murder case. He says the reporter may use the information as long as he identifies the source only as one close to the case. This way the lawyer won't offend witnesses or the judge who may learn about the move first by reading the newspaper.

Background: This is a difficult area, but generally background information is intended to educate and guide the reporter in crafting his story, but the gist of the information possibly may be used later, sometimes only if the source isn't identified. The reporter is free to make it clear that he isn't the original source for the information, but often must be careful to guard the exact nature of the source. Example: The governor's aide briefs reporters on the state's upcoming budget and the rationale behind parts of it so they will be better prepared when a press conference is held later in the week.

Off the Record. This is information that generally may not be published. However, if the reporter confirms the information from another source, then it may be published. Sources frequently say material is off the record, although they very much want to see it in the paper, but not attributed to them.

Often a news source will want to go "off the record" for a few minutes during an on-the-record interview. The reporter has to decide whether he will accept off-the-record information. If he does, he may not use it unless he can get independent corroboration.

Deep Background. This is used almost exclusively in Washington. It is strictly off the record and not to be used in any way immediately. If, later, a story develops, then the outline of the information may be used, but never attributed. Generally, it appears as though the reporter himself is the original source. An example would be the secretary of defense holding a meeting for select reporters to discuss long-range ramifications of a war in the Middle East and what the administration's reaction might be.

Some newspapers will refuse to have their reporters attend a meeting that is conducted under deep background rules because it tends to tie their hands. Likewise, individual reporters often will refuse to accept information that is off the record.

The key to avoiding misunderstandings with reporters is to establish the ground rules at the beginning of the interview. If no rules are set, the interview is on the record.

Michael J. Davies is editor and chairman of The Hartford Courant. Reprinted with permission of Hartford Courant.

Update: Treatment of Cryptosporidiosis in Patients with AIDS

In November 1982, 21 patients with acquired immunodeficiency syndrome (AIDS) and severe, protracted diarrhea caused by cryptosporidiosis were reported; the report concluded that no effective treatment for cryptosporidiosis was known at that time. Since then, 91 additional patients with AIDS experiencing chronic cryptosporidiosis have been reported to the CDC. Although no therapy has been consistently effective in treating them, preliminary reports suggest that a few may have responded to treatment with spiramycin (Rovamycine,* Rhone-Poulenc Pharma, Montreal) or the combination of quinine and clindamycin.

Since December 1982, physicians at the University of Miami, Fla., have used spiramycin to treat seven AIDS patients with chronic cryptosporidiosis; six other AIDS patients with cryptosporidiosis have been treated with spiramycin at five other institutions; and one non-AIDS patient with chronic cryptosporidiosis associated with a bone marrow transplant has received the drug. Thirteen of the 14 patients were adults; they received 1 g of spiramycin orally three or four times per day. The 14th patient, a 2-year-old child, received 500 mg orally twice a day. No adverse effects were attributed to the drug.

Three of the 13 AIDS patients were apparently cured after three to four weeks of spiramycin therapy (ie, all three improved symptomatically, and intestinal biopsies and three successive stool examinations after therapy were negative). Follow-up six to seven months after discontinuation of spiramycin revealed that all three remained asymptomatic. Two have subsequently died from causes related to their underlying immunodeficiency—one with Kaposi's sarcoma, the other with *Pneumocystis carinii* pneumonia.

In an additional three AIDS patients, gastrointestinal symptoms improved rapidly with spiramycin (in two cases, within 48 hours of starting the drug), but these patients continued to have *Cryptosporidium* in their stools. Spiramycin was continued for variable periods of time, but when therapy was stopped, diarrhea in each patient promptly recurred. On reinitiation of spiramycin, two of the three again improved, but the third continued to have severe diarrhea and has since died. One of the two surviving patients had *Cryptosporidium* detected in his stool at weekly intervals for the first 3½ months of therapy. The patient recently had three negative stools, and spiramycin was stopped; he now has been off therapy for two weeks and remains asymptomatic.

The remaining seven AIDS patients did not respond symptomatically or parasitologically to spiramycin. Three, however, died within two to seven days after starting spiramycin. None of the deaths was attributed to spiramycin.

A non-AIDS patient with chronic cryptosporidiosis, acquired after receiving a bone marrow transplant, also improved with spiramycin therapy. She began spiramycin after suffering from severe, watery diarrhea and abdominal cramps for six weeks; within 24 hours, her cramps had resolved and her diarrhea had improved, and two weeks later, she was having one bowel movement a day. After three weeks of therapy, a stool examination was negative for *Cryptosporidium.* The CDC has also received six reports of AIDS patients and one bone marrow transplant patient with cryptosporidiosis who were treated with a combination of quinine and clindamycin, both given orally. Two patients did not respond after seven to 14 days of therapy. In three others, the drugs were discontinued because of adverse effects; one developed a severe rash; another, severe vomiting; the third, thrombocytopenia. Symptoms improved in two of these three patients during the first few days of therapy. The sixth patient had acute cholecystitis and diarrhea associated with *Cryptosporidium* of the cystic duct and intestines. He received 300 mg of clindamycin and 250 mg of quinine, given orally four times a day. Within two days of initiating therapy, the patient's diarrhea resolved, but stool examinations after therapy continued to show occasional *Cryptosporidium.* A seventh patient, who developed chronic cryptosporidiosis after receiving a bone marrow transplant, also received oral quinine and clindamycin; the patient showed no clinical improvement despite two weeks of therapy.

Reported by M Whiteside, MD, C MacLeod, MD, M Fischl, MD, G Scott, MD, Miami, Fla; J Cain, MD, M Wolfe, MD, Washington, DC; T Brasitus, MD, Chicago; B Blazar, MD, Minneapolis; R Glickman, MD, New York City, R Soave, MD, D Kaufman, MD, New York; E Buckley, MD, Durham, NC; G Poporad, MD, Elkins Park, PA; S Gluckman, MD, W Lipshutz, MD, R Kaplan, MD, Philadelphia; D Portnoy, MD, M Zaklos, MD, Montreal; AIDS Activity, Div of Host Factors, Protozoal Diseases Br, Div of Parasitic Diseases, Center for Infectious Diseases, CDC.

—Morbidity and Mortality Weekly Report (Vol. 33/Nos. 9, 10, 1984), Centers for Disease Control, Atlanta.

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*Use of trade names is for identification only and does not imply endorsement by the Public Health Service or the US Department of Health and Human Services.

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Council Meeting

Thursday, March 15, 1984
160 St. Ronan Street, New Haven, CT

Attendance

Present in addition to the Chairman, Dr. G. W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahamed, Ahrens, Alisberg, Beck, Bobruff, Canzonetti, Czarsty, Dardick, Doctor, Freedman, Friedberg, James, Kaess, Kamens, McDonnell, Mendillo, Orphanos, Parrella, Petrie, Ragusa, Sadowski, Sweet, Villa, Waldron and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Sweeney, Mr. Tomat (FCMA), Mrs. Harney (NHCMA), Mrs. Sandler (President, Auxiliary) and Dr. Lee Morisy (Postgraduate Section).

Absent were: Drs. Concannon, Keefe, Reyelt, Sharon, Sullivan and Whalen. Also absent was Dr. Fabro.

Reports from Physicians Serving on State and Federal Agencies

The Council has been made aware of a primary care plan pilot program conceived by the Department of Income Maintenance to be implemented in Middletown in the near future. Our Liaison Committee with the Department of Income Maintenance has been asked to investigate this matter and report to the Council.

Dr. Abbot noted that he had recently been appointed as the CSMS nominee to the Statewide Health Coordinating Council (SHCC) as the Provider Representative-At Large. Also nominated to the SHCC was Dr. Eslami, as the Provider Representative from HSAV.

Report of the President

a. President Daniel W. Doctor, M.D., reported on a March 1 meeting sponsored by the New Haven Chamber of Commerce regarding the "ALL-PAYOR" legislation. Dr. Doctor represented the CSMS on a panel of four participants and emphasized in his remarks that there was no need for such legislation in Connecticut.

b. The President also reported on his appearance before a Republican caucus at the Capitol on March 15 in which he reiterated the Society's strong objections to the "ALL-PAYOR" legislation and pointed out the need for quality safeguards.

Council Chairman Guy W. Van Syckle, M.D., suggested that the Report of the Committee on Statewide Medical Planning be considered by the Council in conjunction with the Report of the President since both items dealt almost entirely with the issue of "ALL-PAYOR" legislation.

Roger S. Beck, M.D., Chairman of the Committee on Statewide Medical Planning, reviewed for the Council the working paper developed by his committee which had been included with the agenda.

It was VOTED to designate a small group from the Council to meet briefly and develop a list of amendments pertaining to the "ALL-PAYOR" legislation for submission to and consideration of the Council. (The group was comprised of Drs. Beck, Bobruff, Canzonetti, Doctor and Friedberg. Also Mr. Norbeck and Mr. Fiorentino).

The group met and developed a list of ten amendments. After discussion, the Council VOTED to accept the following ten amendments as the CSMS position on the "ALL-PAYOR" (SB 61) legislation:

1. Eliminate Commissioners from Task Force, make one ex-officio.
2. Composition of Task Force—Appointed by the Governor from a list of constituents—1 CHA, 1 CSMS, 1 CNA, 1 labor, 1 public, co-chairs of Public Health Committee and ranking members—4, 1 Blue Cross, 1 insurance industry.
3. Require CHHC to incorporate Task Force recommendations into implementation of the prospective payment system ("shall" rather than "may").
4. Define Peer Review Organization as CPRO.
5. Require simple majority vote of Task Force.
6. Professional Advisory Committee—composition: two physicians appointed by CSMS, CHA, Labor and two nurses.
    a. change wording from *may* to *shall*
    b. require permanent nature to Committee
7. Protection of Confidentiality for patients, doctors and hospitals.
8. Commissioner should *not* be able to bargain with HMO's for discounts.

9. Section 14—eliminate (CHHC Commissioner)
10. Appeals Mechanism to independent outside body other than CHHC.

Health Policy Agenda

CSMS Representative Frank K. Abbot, M.D., and Stewart J. Petrie, M.D., distributed copies of the AMA Health Policy Agenda Task Force Interim Report. The study will probably take three years to complete and by summer it is hoped to reach the half-way mark. Council members were invited to review the report and send any comment they may have on the principles covered to Drs. Petrie or Abbot.

AMA Announcement on Physician Freeze

After discussion of the action taken by the AMA Board of Trustees, it was VOTED to support the following resolution to the House of Delegates for approval. Dr. Jerome Freedman wished it to be noted that he voted against this resolution.

RESOLVED: that the Connecticut State Medical Society is concerned about the provision of cost effective medical care and therefore endorses the decision of the Board of Trustees of the American Medical Association to send a letter to each physician in the United States, urging him or her to:

1. Freeze fees for a one-year period, beginning immediately; and
2. Continue to take into account the financial circumstances of each of his or her patients—especially the unemployed, the uninsured, and those under Medicare—and to accept reduced fees when warranted.

Report of the Subcommittee on Preliminary Study of Nominations

The Chairman of the Council read a letter from Dr. William Whalen, President Elect that he regretted that he would not be able to serve as President for the 1984-85 term. Following discussion, it was VOTED to reverse the order of succession to the Presidency with Dr. Joseph Sadowski, current Vice-President being elevated to the Presidency and Dr. William Whalen would remain as President-Elect. With several other minor amendments, it was VOTED to approve the report of the Subcommittee and to transmit to the House of Delegates the complete slate of nominees for election, with Council recommendation for approval by the House of Delegates.

It was further VOTED to request the Subcommittee on Preliminary Study of Nominations to consider a resident member for each committee and that the Council invite the resident section to supply the chairmen of each CSMS committee with names of members who would be interested in serving on committees ex-officio, while the Bylaw Committee studies whether a bylaw change is necessary.

Report from the Committee on Legislation

Isadore H. Friedberg, M.D., Chairman of the CSMS Committee on Legislation, discussed the proposed Impaired Physician legislation and mentioned that the confidentiality issue had been resolved. It is expected that the legislation will move rapidly through the legislature with support of CSMS. Dr. Friedberg expressed his belief that it might well be the best such legislation in the country.

Connecticut Peer Review Organization Update

Correspondence from Dr. Whalen, CPRO President, to the Society detailing CPRO progress and requesting assistance in their search for a Medical Director and four Regional Medical Consultants, was reviewed and accepted as information.

Hospital-Medical Staff Section

After discussion of correspondence between Drs. Michael A. Dean, Stewart Petrie and Mr. Timothy Norbeck regarding the establishment of a CSMS Hospital-Staff Section, it was VOTED to have the President of CSMS convene an organizational meeting of that section.

Communication Re: Department of Health Physician Directory

Correspondence between Mr. Stephen Harriman and Dr. Jerome K. Freedman was reviewed concerning the publication of the Physician Directory. It was VOTED to write a letter to Dr. Lloyd informing him that this directory was very useful to physicians and also to others in locating licensed physicians, and that it was felt that the registration fee should more than offset the cost of publication. The Chairman of the CMEB will be notified of this action.

Section Meetings

Communications from the Sections on Gastroenterology and Otolaryngology concerning the notice they received informing the groups that this was the third year they did not meet during the annual meeting of the CSMS which is usually cause to disband the section were reviewed. Following discussion of the correspondence and the reasons for non-compliance, it was VOTED to grant the sections one more year to comply with the CSMS Bylaws.

Life Members

It was VOTED to receive for information the list of Life Members which is as follows:

Life Members

Name	Town	Effective Date
Lamson Blaney	Mansfield Center	1/1/84
Walter McKeand Brown	Groton	1/1/84
Frank G. Elliott	Stratford	1/1/84
Bernard J. Kaplan	Hartford	1/1/84
John A. Kirchner	New Haven	1/1/84
James D. McGaughey	Wallingford	1/1/84
John G. Murray	Greenwich	1/1/84

Miscellaneous

CSMS-CBA Joint Meeting: Stewart J. Petrie, M.D., reported on a recent joint meeting held with members of the Connecticut Bar Association. His report was received for information.

Report from the Committee on Public Relations: A report from the Committee on Public Relations recommended that Gerald Labriola, M.D., be the CSMS spokesman for public service type television announcements. After discussion, it was VOTED to refer the request back to the Committee on Public Relations for further study and specific information as to the overall cost of such a program and if public service time could be utilized.

"ALL-PAYOR" Legislation: Robert R. McDonnell, M.D., urged the Council to support a public relations effort to combat the CBIA radio tapes promoting the "ALL-PAYOR" legislation. It was VOTED to appropriate up to $10,000 to develop and produce several CSMS radio spots if such an effort was deemed helpful by the Society's Legislative Counsel. Mr. Norbeck suggested that the first tape could be available on the following day and that he would discuss it with several of the CSMS officers and others involved in the Committee on Legislation. NOTE—CSMS did produce two radio tapes for airing on three stations (WEZN, WELI & WTIC) and generated considerable discussion on the legislation including numerous free radio interviews, etc.

Joint Conference Committee with Pharmaceutical Association: It was VOTED to approve the statement of this committee that "due to its high potential for abuse as well as its recognized medical usefulness, we suggest that Dilaudid (R) be reformulated and that Naloxone be added to the product to reduce its abuse potential."

It was requested that CSMS make this recommendation directly to the manufacturer, or to the AMA, or both.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on March 15, 1984. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

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Please send them to:
J. Alfred Fabro, M.D., Editor
Connecticut Medicine
160 St. Ronan Street
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References:
1. Stone PH, Turi ZG, Muller JE: Efficacy of nifedipine therapy for refractory angina pectoris. *Am Heart J* 104:672-681, September 1982.
2. Antman E, Muller J, Goldberg S, et al: Nifedipine therapy for coronary-artery spasm: Experience in 127 patients. *N Engl J Med* 302:1269-1273, June 5, 1980.

BRIEF SUMMARY
PROCARDIA® (nifedipine) **CAPSULES** For Oral Use

INDICATIONS AND USAGE: I. Vasospastic Angina: PROCARDIA (nifedipine) is indicated for the management of vasospastic angina confirmed by any of the following criteria: 1) classical pattern of angina at rest accompanied by ST segment elevation, 2) angina or coronary artery spasm provoked by ergonovine, or 3) angiographically demonstrated coronary artery spasm. In those patients who have had angiography, the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina, provided that the above criteria are satisfied. PROCARDIA may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed, e.g., where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm, or when angina is refractory to nitrates and/or adequate doses of beta blockers.

II. Chronic Stable Angina (Classical Effort-Associated Angina): PROCARDIA is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents.

In chronic stable angina (effort-associated angina) PROGARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in those patients are incomplete.

Controlled studies in small numbers of patients suggest concomitant use of PROCARDIA and beta blocking agents may be beneficial in patients with chronic stable angina, but available information is not sufficient to predict with confidence the effects of concurrent treatment, especially in patients with compromised left ventricular function or cardiac conduction abnormalities. When introducing such concomitant therapy, care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs. (See Warnings.)

CONTRAINDICATIONS: Known hypersensitivity reaction to PROCARDIA.

WARNINGS: Excessive Hypotension: Although in most patients, the hypotensive effect of PROCARDIA is modest and well tolerated, occasional patients have had excessive and poorly tolerated hypotension. These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment, and may be more likely in patients on concomitant beta blockers.

Severe hypotension and/or increased fluid volume requirements have been reported in patients receiving PROCARDIA together with a beta blocking agent who underwent coronary artery bypass surgery using high dose fentanyl anesthesia. The interaction with high dose fentanyl appears to be due to the combination of PROCARDIA and a beta blocker, but the possibility that it may occur with PROCARDIA alone, with low doses of fentanyl, in other surgical procedures, or with other narcotic analgesics cannot be ruled out. In PROCARDIA treated patients where surgery using high dose fentanyl anesthesia is contemplated, the physician should be aware of these potential problems and, if the patient's condition permits, sufficient time (at least 36 hours) should be allowed for PROCARDIA to be washed out of the body prior to surgery.

Increased Angina: Occasional patients have developed well documented increased frequency, duration or severity of angina on starting PROCARDIA or at the time of dosage increases. The mechanism of this response is not established but could result from decreased coronary perfusion associated with decreased diastolic pressure with increased heart rate, or from increased demand resulting from increased heart rate alone.

Beta Blocker Withdrawal: Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina, probably related to increased sensitivity to catecholamines. Initiation of PROCARDIA treatment will not prevent this occurrence and might be expected to exacerbate it by provoking reflex catecholamine release. There have been occasional reports of increased angina in a setting of beta blocker withdrawal and PROCARDIA initiation. It is important to taper beta blockers if possible, rather than stopping them abruptly before beginning PROCARDIA.

Congestive Heart Failure: Rarely, patients, usually receiving a beta blocker, have developed heart failure after beginning PROCARDIA. Patients with tight aortic stenosis may be at greater risk for such an event.

PRECAUTIONS: General: Hypotension: Because PROCARDIA decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of PROCARDIA is suggested. Close observation is especially recommended for patients already taking medications that are known to lower blood pressure. (See Warnings.)

Peripheral edema: Mild to moderate peripheral edema, typically associated with arterial vasodilation and not due to left ventricular dysfunction, occurs in about one in ten patients treated with PROCARDIA. This edema occurs primarily in the lower extremities and usually responds to diuretic therapy. With patients whose angina is complicated by congestive heart failure, care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

Drug interactions: Beta-adrenergic blocking agents: (See Indications and Warnings.) Experience in over 1400 patients in a non-comparative clinical trial has shown that concomitant administration of PROCARDIA and beta-blocking agents is usually well tolerated, but there have been occasional literature reports suggesting that the combination may increase the likelihood of congestive heart failure, severe hypotension or exacerbation of angina.

Long-acting nitrates: PROCARDIA may be safely co-administered with nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

Digitalis: Administration of PROCARDIA with digoxin increased digoxin levels in nine of twelve normal volunteers. The average increase was 45%. Another investigator found no increase in digoxin levels in thirteen patients with coronary artery disease. In an uncontrolled study of over two hundred patients with congestive heart failure during which digoxin blood levels were not measured, digitalis toxicity was not observed. Since there have been isolated reports of patients with elevated digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing PROCARDIA to avoid possible over- or under-digitalization.

Carcinogenesis, mutagenesis, impairment of fertility: When given to rats prior to mating, nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose.

Pregnancy: Category C. Please see full prescribing information with reference to teratogenicity in rats, embryotoxicity in rats, mice and rabbits, and abnormalities in monkeys.

ADVERSE REACTIONS: The most common adverse events include dizziness or light-headedness, peripheral edema, nausea, weakness, headache and flushing each occurring in about 10% of patients, transient hypotension in about 5%, palpitation in about 2% and syncope in about 0.5%. Syncopal episodes did not recur with reduction in the dose of PROCARDIA or concomitant antianginal medication. Additionally, the following have been reported: muscle cramps, nervousness, dyspnea, nasal and chest congestion, diarrhea, constipation, inflammation, joint stiffness, shakiness, sleep disturbances, blurred vision, difficulties in balance, dermatitis, pruritus, urticaria, fever, sweating, chills, and sexual difficulties. Very rarely, introduction of PROCARDIA therapy was associated with an increase in anginal pain, possibly due to associated hypotension.

In addition, more serious adverse events were observed, not readily distinguishable from the natural history of the disease in these patients. It remains possible, however, that some or many of these events were drug related. Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2%. Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0.5% of patients.

Laboratory Tests: Rare, mild to moderate, transient elevations of enzymes such as alkaline phosphatase, CPK, LDH, SGOT, and SGPT have been noted, and a single incident of significantly elevated transaminases and alkaline phosphatase was seen in a patient with a history of gall bladder disease after about eleven months of nifedipine therapy. The relationship to PROCARDIA therapy is uncertain. These laboratory abnormalities have rarely been associated with clinical symptoms. Cholestasis, possibly due to PROCARDIA therapy, has been reported twice in the extensive world literature.

HOW SUPPLIED: Each orange, soft gelatin PROCARDIA CAPSULE contains 10 mg of nifedipine. PROCARDIA CAPSULES are supplied in bottles of 100 (NDC 0069-2600-66), 300 (NDC 0069-2600-72), and unit dose (10x10) (NDC 0069-2600-41). The capsules should be protected from light and moisture and stored at controlled room temperature 59° to 77°F (15° to 25°C) in the manufacturer's original container.

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IN MEMORIAM

AMDUR, MILLARD J., Yale, 1964. Dr. Amdur was a psychiatrist in the Windham area since 1965. He was on the staff of the Natchaug Hospital since 1972. Dr. Amdur was the chief of medical services of United Social and Mental Health Services in Danielson and in 1983 was appointed its medical director. He was a member of the Windham County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 15, 1984 at the age of 46.

CANTY, WILLIAM P., University of Dublin, Ireland, 1954. Dr. Canty was an obstetrician/gynecologist in the Windham area since 1965 and at the time of his death was affiliated with Day Kimball Hospital. He was a member of the Windham County Medical Association and the Connecticut State Medical Society; died March 20, 1984 at the age of 53.

DELOHERY, C. LEO, Temple University, 1926. Dr. Delohery was a general practitioner in the Fairfield area 1927, and was on the staff of the Danbury Hospital. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died March 8, 1984 at the age of 86.

GOLD, LOUIS, New York Medical College, 1932. Dr. Gold was a psychiatrist in the Hartford area since 1932 and was at the time of his death, an Emeritus attending at Mt. Sinai Hospital and University of Connecticut Health Center, John Dempsey Hospital (formerly McCook). He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died April 7, 1984 at the age of 76.

O'CONNELL, PATRICK H., Loyola, 1929. Dr. O'Connell was a general practitioner in the New London area since 1933. He was a staff attending at Backus Hospital. Dr. O'Connell was a member of the New London County Medical Association, the Connecticut State Medical Society and the American Medical Association; died December 22, 1983 at the age of 87.

SCHUPACK, SAMUEL D., Tufts University, 1924. Dr. Schupack was a pediatrician in the Hartford area since 1925. He was on the staff of New Britain General Hospital and Hartford Hospital. Dr. Schupack was an army veteran of World War I. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 26, 1984 at the age of 85.

SCOVILLE, WILLIAM B., University of Pennsylvania, 1932. Dr. Scoville practiced neurosurgery in the Hartford area since 1939 and in that same year he founded Hartford Hospital's Neurosurgery department and remained its chief until 1967. He was an emeritus clinical professor of neurosurgery at Yale University School of Medicine. Dr. Scoville was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died February 25, 1984 at the age of 78.

SHURE, A. LEWIS, Tufts University, 1927. Dr. Shure was an orthopedic surgeon in the New Haven area since 1927. He was on the staff of Yale New Haven Hospital and The Hospital of St. Raphael. Dr. Shure served in the U.S. Army during World War II and rose to the rank of major. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died April 10, 1984 at the age of 82.

SIRICA, A. EUGENE, Johns Hopkins, 1930. Dr. Sirica was a general practitioner in the New Haven area since 1932 during which time he served in the U.S. Army during World War II. He served for 10 years as the attending physician in the Emergency Room of Waterbury Hospital, retiring in 1978. Dr. Sirica was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 27, 1984 at the age of 80.

STETSON, HARRY W., University of Vermont, 1906. Dr. Stetson was a general practitioner in the New Haven area since 1926 and was on the staff of the Milford Hospital. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died March 14, 1984 at the age of 100.

WINECK, MORRIS S., University of Vermont, 1915. Dr. Wineck was a general practitioner in the Hartford area since 1919. He was a member of the medical staff of Mount Sinai Hospital and was a member of the courtesy staff at Hartford Hospital and St. Francis Hospital. Dr. Wineck was the Hartford police surgeon for 41 years. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died March 24, 1984 at the age of 93.

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PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Connecticut—Full-time Emergency Physician, seashore community of 50,000. Write Allan Brandt, M.D., Chairman, Milford Hospital, Department of Emergency Medicine, 2047 Bridgeport Ave., Milford, CT 06460.

Primary Care MD's needed for Free-Standing Emergency Centers in Central CT. Family Practice/General Practice/ER experience desirable. Full and part-time positions available days, evenings, and weekends. $50-60,000 annual salary for 40 hour week depending on experience/qualifications. With option to become part-owner. Direct resumés/inquiries to: Dr. Edward Ewald, 1 Corporate Dr., Windsor Locks, CT 06096.

FAMILY PRACTICE

Seeking an associate in Family Practice. Located in a central Connecticut Community, 8 to 10 miles from two modern teaching hospitals. Fully equipped office includes Laboratory and X-ray Unit. Ultimate Partnership if desired. Send Curriculum Vitae to CSMS/DAR.

INSTITUTIONAL MEDICINE

BC/BE primary care physicians needed to join new immediate medical care facility in East Hartford. Please reply with C.V. and date of availability to CSMS. INST/MTG.

Walk-In Medical Services is seeking full and part-time physicians to work in a convenience medical facility in Orange, CT. Family Practice/Internal Medicine preferred. Reply to CSMS, INST/RBH.

INTERNAL MEDICINE

Wanted: Internist to set up active practice in internal medicine and geriatrics. This would be in association with young internist currently with very busy geriatric and nursing home practice in Branford, CT. If interested, please send CV to CSMS, IM/ADW.

Established Internal Medical Practice—New Haven Area. Busy, Prestigious, Expense Sharing Group—Challenging For Ambitious Compassionate Physician. Reply to CSMS, IM/SM

OBSTETRICS

Obstetrician needed in rural area of eastern Connecticut. Opportunity for private practice associated with accredited acute care community hospital fully served by other specialties and state-of-art support services. Large catchment area with large underserved patient populations. For information, send CV to CSMS, OB/CFS.

OBSTETRICS/GYNECOLOGY

Board certified or eligible Ob/Gyn wanted to associate with older Ob/Gyn with outlook of taking over practice. Situated in Southwestern Connecticut. Write, CSMS, OBGYN/JM.

OCCUPATIONAL HEALTH

Physician needed to direct Employee Clinic for 4,500 employees and students at Hartford Hospital, a 1000 bed tertiary care general hospital, affiliated with University of Connecticut School of Medicine. Future growth potential of position may include development of community occupational health service. Candidates should have training and experience leading to Board Certification in Occupational Medicine. Please send C.V. to: Mrs. Judith Kerrigan, Coordinator, Professional Recruitment, Hartford Hospital, 80 Seymour Street, Hartford, CT 06115. Equal Opportunity/Affirmative Action Employer.

OTOLARYNGOLOGY

Three-Physician Ear, Nose & Throat Group in Central Connecticut seeking fourth Associate, actively engaged in general Ear, Nose & Throat and head and neck practice. Reply to CSMS, OTO/IG.

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Part-time association for competent and personable Radiologist. No special expertise necessary. Hospital and office practice in central Connecticut. Reply CSMS, PT/JH.

PRACTICE FOR SALE

Internal Medicine/Family Practice. Unusual opportunity to assume high-profile practice in mid Fairfield County. For details respond to CSMS, PRAC/OPP.

Established solo general/family practice for sale in Stratford, Fairfield County: Well-equipped, spacious office with laboratory and X-Ray in modern professional building-leased. Suitable for family practice or internal medicine. Close to large teaching hospital. Gross $130,000 plus, Price $60,000, Terms negotiable. Available now. M.D. relocating. Reply to John R. Graham M.D., 33 King Street, Stratford, CT 06497, Office Phone (203) 377-6196, Home Phone (203) 375-9767.

Psychiatric Practice for Sale. Central Connecticut area. Practitioner moving to warmer climate. Write, CSMS, SALE/TRK.

Medical practice and fully equipped medical office (including a Ritter table) available. Convenient location in Wethersfield, just over the town line. Ample free parking. Ideal for Internal Medicine or Family Practice or OB/GYN. Available 3rd week in June. Write CSMS, SALE/NESJ.

PRIMARY CARE

Growing Connecticut based multicenter, episodic, primary care practice seeks outstanding IM/FP/ER trained physicians to join in high quality high volume diagnostic medicine. Competitive salary, bonus program, potential partnership. Ongoing and future clinical research. Positions available now. CV to CSMS, Inst/DC.

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ANESTHESIOLOGY

Sept. '84. Age 32. AB elig. MD and Int., Calicut Medical College, India; Res., University René Descartes, Paris, France and Allegheny General Hospital, Pittsburgh, PA. Prefers to be in a hospital of at least 250 beds and/or group practice. Write, Jayam Krishna Iyer, M.D., 436 TA, Chatham Park Dr., Pittsburgh, PA 15220.

Aug. '84. Age 30. Presently in practice. FLEX. AB elig. MD, Baroda Medical College, India; Int., Bronx Lebanon Hospital, Bronx, NY; Res., Mount Sinai Medical School and Long Island Jewish-Hillside Medical Center, NY. Prefers group, assoc. or institutional type practice in a small to medium-sized community. Write, R.S. Saraiya, M.D., 88-25A, 153rd St., #4F, Jamaica, NY 11432.

FAMILY PRACTICE

Available within two months of notification. Licensed in Connecticut. Presently in practice. Age 34. Nat'l bds. AB cert. MD, University of Florida; Int. and Res., St. Margaret's Hospital, Pittsburg, PA. Prefers group or associate type practice in medium-sized community (Southern Connecticut). Write, Larry Novik, M.D., 277 West 10th St., #11-H, New York, NY 10014.

INSTITUTIONAL/INDUSTRIAL MEDICINE

OCCUPATIONAL. April '84. Age 69. Licensed in Connecticut. Nat'l bds. AB cert. MD, Cornell; Int., two years rotating; USAF-MC, four years. Available ft/pt staff, Hartford area. Write, Lamson Blaney, M.D., Box 154, Mansfield Center, CT 06250.

June '84. Age 59. Licensed in Connecticut. Presently in practice. Nat'l bds. AB cert. MD, Georgetown University; Int., Georgetown Hospital, Washington, DC; Res., B.U. University Hospital, Boston City Hospital. Desires position in Occupational Medicine. Nine years experience in Emergency Medicine. Eight years experience in Occupational Medicine. For futher information contact, Louis Z. Fauteux, Jr., M.D., 141 Weston St., Hartford, CT 06101.

INTERNAL MEDICINE

July '84. Age 32. Nat'l bds. AB elig. MD, Autonomous University of Guadalajara, Mexico; Int. and Res., Prince George's General Hospital, Cheverly, MD. Prefers solo, group or associate type practice. Write, James E. Sullivan, M.D., 5009 Cheyeenne Place, College Park, MD 20740.

HEMATOLOGY/MEDICAL ONCOLOGY. July '85. Age 31. Nat'l bds. AB cert. MD, State University of NY—Downstate Medical Center College of Medicine; Int. and Res., St. Vincent's Hospital and Medical Center, NY; Fellowship, University of Rochester Medical Center, Strong Memorial Hospital, NY. Prefers solo, group, associate or institutional type practice in a medium to large-sized community. Would consider full-time hospital based practice. Write, Denis Fitzgerald, M.D., 80 Cimarron Drive, Rochester, NY 14620.

NEPHROLOGY. Aug. '84. Age 33. Nat'l bds. AB cert. MD, NY University; Int., L.A. County—U.S.C. Medical Center; Res. and Fellowship, Kaiser Foundation Hospital, Los Angeles, CA. Prefers group or institutional type practice within several hours of greater New York area. Write, Richard B. Schwarz, M.D., 8300 DeLongpre Ave., #204, Los Angeles, CA 90069.

NEUROLOGY

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ORTHOPEDICS

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ORTHOPEDICS —Continued

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PATHOLOGY

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PEDIATRICS

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July '84. Age 35. Licensed in Connecticut. FLEX. AB elig. MD, Univ. de Liege, Belgium; Int. and Res., Univ. of Connecticut. Is most interested in either multi-specialty or a group and also would consider joining an exchange solo practice. Write, Thomas Eder, M.D.,325 N. Glendora Ave., Glendora, CA 91740.

July '84. Age 31. FLEX. M.B.B.S. and Int., University of Jabalpur, Medical College, Jabalpur, M.P., India; Res., Victoria Hospital, Jabalpur, M.P., India, Clara Swain Hospital, Bareilly, U.P., India and Illinois Masonic Medical Center, Chicago, IL. Prefers group or associate type practice. Write, Satish Kumar Shrivastava, M.D., 856 West Nelson, Apt. #1506, Chicago, IL 60657.

PSYCHIATRY

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RADIOLOGY

DIAGNOSTIC. Aug. '84. Age 43. Presently in practice. Nat'l bds. AB cert. MD, Hannemann Medical University, Philadelphia, PA; Int., Roosevelt Hospital, NY; Res., NYU-Bellevue Medical Center, NY; Fellowship, Brigham and Women's Hospital, Harvard Medical School, Boston, MA. Prefers group, assoc. or institutional type practice in a medium to large-sized community. Has had nine years of general radiology including angio, nuclear medicine and ultrasound. Write, Eugene S. Barasch, M.D., P.O. Box 58, Harvard, MA., 01451.

SURGERY

VASCULAR. July '84. Age 31. Nat'l bds. AB elig. MD, Mt. Sinai School of Medicine, NY; Int., Res., and Fellowship, Mt. Sinai Hospital, NY. Prefers group or associate type practice. Write, Charles M. Miller, M.D., 1763 Second Ave., Apt. 21L, New York, NY 10128.

SURGICAL ONCOLOGY. Summer '84. Presently in practice. Age 35. FLEX. AB cert. MD, Christian Medical College (University of Madras, Vellore, India); Int., New Jersey College of Medicine and Dentistry, Neward, NJ; Res., Creighton University, Omaha, NB; Fellowship, Ellis Fischel State Cancer Hospital, Columbia, MO. Prefers solo, group or associate type practice in a medium to large-sized community. Write, CSMS, RVP/SUR.

UROLOGY

July '84. Age 31. Nat'l bds. AB elig. MD, SUNY Stony Brook, NY; Surgical Int. and Res., St. Vincent's Hospital, NYC; Urological Res., Beth Israel Hospital, NYC. Prefers group, assoc., institutional or industrial type practice in a small to medium-sized community. Write, Susan G. Kaplan, M.D., 353 East 17th Street, Apt. 9C, New York, NY 10003.

Management of Spina Bifida in the Newborn Infant

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ABSTRACT—Spina bifida as manifest by meningocoele, myelomeningocoele, and lipomyelomeningocoele is discussed in terms of embryology, clinical problems, diagnostic modalities, treatment, and management decisions.

Introduction

Although the management of an infant with spina bifida may present complex medical and social problems that require the input of a skilled team of health professionals this care does not represent a moral dilemma. Spina bifida, or the variable failure of fusion of the neural tube between the third and fourth weeks of gestation, represents a spectrum of disease ranging from a simple defect in the bony laminal arch at a single level in the spinal column to a complete craniorachisis with absent bony arches and protruding neural tissue over many spinal segments.[1,2] The most troublesome forms of spina bifida include meningocoeles, myelomeningocoeles, and lipomyelomeningocoeles, for the infants present at the time of birth or now more commonly in utero with obvious spinal column deformities and frequently protruding neural tissue; such patients may suffer malformation of the brainstem, cerebellum and cerebral hemispheres, as well as hydrocephalus and renal and orthopedic problems.

Clinical Problems

The neonate with meningocoele, a protrusion of the spinal meninges with associated spinal fluid accumulation, or myelomeningocoele, in which neural tissue may also be located, presents four immediate neonatal problems: that of the "open" and frequently leaking back with directly exposed neural tissue, the issue of hydrocephalus, the presence of Arnold-Chiari malformation, and associated anomalies. Head size alone is not necessarily indicative of hydrocephalus, as many children will develop progressive ventricular enlargement following closure of the back defect. The one group of these children who almost never develop hydrocephalus are those with lipomyelomeningocoeles which have adipose tissue in the caudal end of the spinal cord. Almost all patients with spina bifida have a type II Arnold-Chiari malformation, or caudal displacement of the brainstem and cerebellar tonsillar herniation. Although most newborn infants are asymptomatic from this anomaly, some develop vocal cord paresis, tongue weakness, difficulty swallowing, and even apnea. Finally, a wide range of other anomalies, ranging from chromosomal anomalies to congenital heart defects or extensive anterior defects such as extrophies may be found in conjunction with spina bifida.

Secondary problems in this population are usually related to infection. Newborns have limited abilities to localize infectious processes, and many infections tend to become generalized. The open back serves as a direct route into the nervous system for bacterial infection; thus a local infection at a repaired myelomeningocoele site, for example, may also lead to sepsis and meningitis. Shunts for hydrocephalus effectively treat the ventricular enlargement with raised intracranial pressure, but also cross significant anatomic barriers as fluid is drained from the ventricular system to the peritoneal cavity or other site for cerebrospinal fluid absorption. In addition, as a foreign body, they represent a significant risk for infection. The urinary tract with its incomplete innervation is also a source of infection and dilatation of the urinary tract may lead to hydronephrosis.

Another secondary problem for these children is the family's acceptance and realistic understanding of a new

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member who has different abilities, limitations, and needs than may have been expected or that the other children have. Similarly, care givers from obstetrics to pediatrics and subspecialties and more recently the courts and various advocacy groups need as great an understanding as possible about these patients and their particular problems.

Diagnostic Modalities

Newborn infants with spina bifida have benefitted significantly from recent advances in a wide range of diagnostic modalities. The most recent of these is real time ultrasound which permits evaluation of both intracranial contents and spinal anatomy. Ultrasound may be performed at the bedside and appears to be without risks to the developing CNS. As the infant grows, neurodevelopmental testing is being more widely employed in order to assess particular abilities and limitations and to provide an independent means for predicting shunt related problems.

Prenatal diagnosis with ultrasound, amniotic fluid alpha-fetal protein, and more recently from maternal serum alpha-fetal protein provide a means for the early detection of fetuses with spina bifida. Such prenatal diagnosis provides the time and opportunity for the parents to learn about this condition which in most instances will be quite foreign to them. Similarly, delivery and post natal care can be arranged such that individuals and facilities appropriate for care are available.[3,4]

Treatment

Classical treatment for these conditions is directed toward the four primary conditions seen in these patients with attention to the secondary problems durng the clinical course. At present care may begin prenatally if the condition has been so diagnosed. New information is being added to our understanding of these fetuses as increasing numbers have been viewed by ultrasound and animal model studies are carried out. Anecdotal evidence of fetal lower extremity movement in the absence of postnatal movement has begun to accumulate. Thus consideration may be given for Cesarian section as has recently been suggested in instances of large heads or prominent myelomeningocoele sacs in order to protect the head and neural placode from trauma. Fetal repair of the open neural tube and covering tissue has been carried out in the experimental animal. Fetal treatment of hydrocephalus is being carried out on an investigational basis in both the human and animal model. Finally, experience is being gained with peripheral nerve grafting to the lower extremities and sacral roots, and neural regeneration is the subject of intense investigation at many centers.

At the time of delivery an exposed neural placode or arachnoidal membrane, leaking or not, may be colonized with bacteria and drying of the neural tissue begins. Therefore, local care must begin immediately. Initial protection of the open area may be carried out by one of several approaches. The usual approach is to apply saline soaked sponges. Such covering may prevent dessication but does nothing to prevent bacterial colonization; the rough fabric which may stick to the tissue may further traumatize the placode. Gentamicin ointment has been applied but the risk of nephrotoxicity exists with this approach. Silvadine ointment may be used without particular concern for drug adsorption. Finally, covering the area with amnion is another alternative that provides an effective barrier. Amnion may be obtained at the time of the infant's delivery or from another delivery.

Initial operative management is directed toward covering the defect in order to protect the neural tissue and to prevent infection. The type of closure depends upon the size of the lesion, the amount of skin available and the experience of the operating surgeons. Many satisfactory alternatives exist as to exactly how the closure is handled. In some instances primary closure will be possible while in others, tissue mobilization or flaps may be necessary, and occasionally staged procedures may be carried out.[5] With concern in recent years over tethering of the spinal cord (i.e., attachment of the caudal portion of the spinal cord to the spinal canal with deteriotation of lower extremity and/or sacral neurologic function) closure of the neural placode has been advocated in order to prevent or at least decrease the likelihood of such tethering. Whether such closure of the placode is an effective step has not yet been determined.

Management of hydrocephalus is by a shunt, usually of the ventriculoperitoneal type. As discussed with diagnostic modalities ventricular size may be readily assessed in the nursery by ultrasound.

Although rare in the newborn period, a symptomatic Arnold-Chiari malformation is the most common cause of death in this population. Stridor is not an infrequent symptom in these infants and relates to cranial nerve involvement. However, apnea may develop presumably on a central basis from further herniation of the brainstem and cerebellar tonsils and increased angulation of the brainstem with attendant tissue distortion and ischemia. Since stridor and apnea may also be symptoms of raised intracranial pressure, a properly functioning shunt system must be demonstrated. Treatment of a symptomatic Arnold-Chiari malformation in the newborn period has been carried out by a variety of decompressive procedures with a much lower success rate and survival than in the older population.

Associated anomalies although unusual are frequently a very ominous sign in terms of survival and neurodevelopmental outcome.

Secondary problems require continued surveillance for their occurrence and management. As the patient becomes older, secondary problems which are likely to arise include scoliosis, foot deformities, skin breakdown, chronic urinary tract infections, hydromyelia, tethered spinal cord, developmental delay, and psychosocial maladaptation.

Because of the complexity of care which these children require, most areas have organized multispecialty clinics for the children in order to attempt to provide the best access to proper care. However, as with most endeavors, a single dedicated knowledgeable care giver whether parent, pediatrician, or subspecialist is the most important factor with regard to long term management.

Management Decisions

From 1979 through 1980 a series of discussions took place between the faculties of neonatology, pediatric neurology, and pediatric neurosurgery at our institution in order to reach a consensus to the approach of such children. As a part of these discussions, records on all children with spina bifida who were admitted to the Newborn Special Care Unit, Yale-New Haven Hospital were evaluated with regard to diagnosis, complications, and outcome. Briefly, 20 patients were admitted to this institution with this problem between 1977 and 1980. During that time, the anticipated outcome of the children based upon that documented in the literature, primarily that of Lorber, was presented to the parents.[6-14] As might be expected there was significant variation in the information that different attending physicians would present to the parents about expected function and survival. Of these 20 infants, eight families made a prompt decision for surgical management. One of these died secondary to sepsis in the neonatal period. Twelve initially decided against aggressive management. Two had cephalocentesis carried out at delivery and died in the newborn period, and four had other severe anomalies which precluded survival. Of the remaining six, four were treated after one week to four months since they were quite stable aside from a rapidly increasing head circumference. The remaining two were not operated upon; one developed sepsis at several months of age and died, and the other epithelialized his back, developed compensated hydrocephalus, and survived with severe motor and intellectual deficits. Neurodevelopmental testing of the other 11 survivors ranged from 76 to 140 on the Bayley mental score. The earlier treated group has lower extremity function ranging from essentially normal to sacral impairment to paraplegia. However, only one of those infants treated late has significant lower extremity function.

Several conclusions were reached from these discussions despite the small number of patients from this institution and disparity of their survival and outcome from that found in much of the literature. The first was that we were not in a position to make ethical edicts as to the fate of these children, and the second was how we would approach them, their families and each other in light of our first decision. We concluded that a fatal outcome was not a likely event in the majority of cases whether or not they were treated despite reports in the literature to the contrary. In fact, the mortality rate between the two groups, treated and not treated, were surprisingly similar. The intelligence of these children while often not as high as that of siblings in usually within the normal range independent of head size or degree of presenting hydrocephalus. Basing decisions on whether or not to treat upon the amount of lower extremity weakness or paralysis or sacral function was no longer considered acceptable. As a result of these discussions, the position was taken to recommend treatment to all children who did not have an additional lethal congenital anomaly or severe perinatal asphyxia. This formulation sounds rather simplistic, and indeed it probably is, but at the current state of knowledge we do not find ourselves in a position to decide any further. With the ordinary care that a such newborn obtains in the nursery, at home, or in an institution, he is not likely to die. Rather, he is likely to survive with devasting intellectual and physical deficits if left untreated. This does not mean that definitive closure of open defects must be treated immediately or hydrocephalus shunted on an emergency basis. But it does mean that such definitive care should be planned so as to take place under the best circumstances possible. If coexisting primary or secondary problems exist which would make such care futile in terms of survival, then supportive care and feeding must be given.

This approach obviously does not address the issues involved with a wide range of other congenital problems to which the newborn is subject, nor does it address the decisions which parents make in instances of prenatally diagnosed anomalies. We believe that these are best addressed as separate issues. We appreciate the opportunity to utilize this forum to present our own particular views about the newborn with spina bifida and our approach to management. Obviously we have begged the ethical questions to a large extent, but, given our clinical experience, we believe it to be appropriate.

Our experience since 1979 with this approach has been both enlightening and disheartening. There is a consistent common ground that we may use to communicate with one another, to the patient's family, and proceed with management. On the other hand these are extremely difficult patients to manage. There remains a high mortality rate, constant complex care must be given, outcomes are extemely variable, and the presence of serious chronic illness in a family is extraordinarily costly and frequently destructive.

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Duodenal Diaphragm with Midgut Nonrotation in an Adult

A Case Study

JAMES J. MATINO, M.D. AND MICHAEL J. TORTORA, M.D.

ABSTRACT—A case of a duodenal diaphragm associated with midgut nonrotation in an adult is reported.

A discussion of the clinical significance of this previously unreported association of congenital gastrointestinal anomalies follows. It is concluded that gastrointestinal anomalies should be given due consideration in any case of chronic gastrointestinal symptoms not responding to routine therapy.

When congenital gastrointestinal anomalies present as unexpected discoveries in an adult at laparotomy, the welfare of the patient may be jeopardized by an unwary surgeon.[1-3] A case report of a misdiagnosed symptomatic duodenal diaphragm associated with midgut nonrotation in an adult is presented. To our knowledge, such an association of congenital gastrointestinal anomalies has never been reported in the adult.

Case Report

A 57 year old white Italian female complained of intermittant epigastric and hypochondrial pain for over 20 years. The pain has been present more frequently in the Spring and occasionally has been relieved by meals. Typically, two to three hours after meals she would experience pain associated with feelings of fullness relieved by vomiting. She has been intolerant of solids for years, existing on liquids and mashed foods.

Multiple Upper G.I. Series have been performed over the years and all were consistent with marked peptic deformity of the duodenal bulb and midgut nonrotation. Treatment with antacids and more recently Cimetidine have produced no improvement.

Her most recent X-ray study revealed a constriction in the midportion of the duodenal bulb with two ulcers in the bulb, consistent with peptic ulcer disease. (Figure 1) The nonrotation involved the third and fourth portions of the duodenum with the proximal jejunum located in the right upper quadrant. (Figure 2) A Barium Enema was consistent with midgut nonrotation with the terminal ileum entering the left lower quadrant cecum from the right side.

The patient was not endoscoped, and she underwent surgery. Exploration was consistent with midgut nonrotation. Congenital fibrous bands (Ladd's Bands) overlying the duodenum were lysed, essentially

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kocherizing the duodenum. A truncal vagotomy was then performed and an antrectomy begun. After division of the duodenum below the pylorus, digital examination and direct inspection revealed a tight duodenal web in its second portion! (Figure 3) With this finding, the duodenum was closed and antrectomy was completed with a Billroth II reconstruction. Because of its aberrant location, an appendectomy was performed.

The post-operative course was uneventful except for mild gastric stasis that responded to metaclopramide.

Surgical pathology revealed chronic antral gastritis and duodenitis.

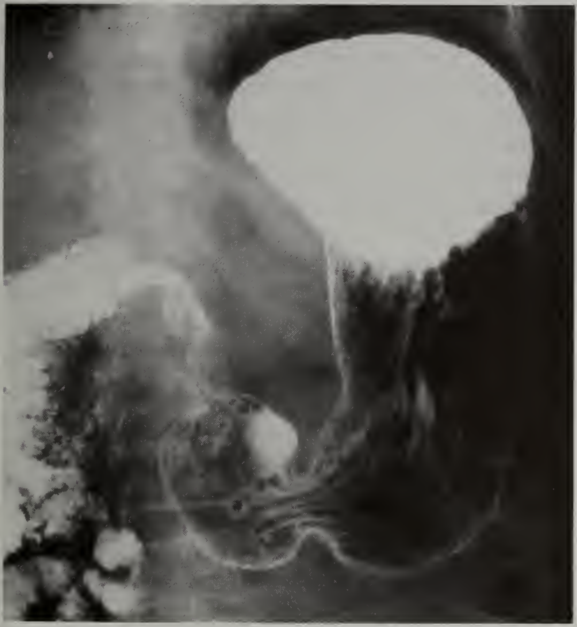

Figure 1
Marked deformity of duodenal bulb.

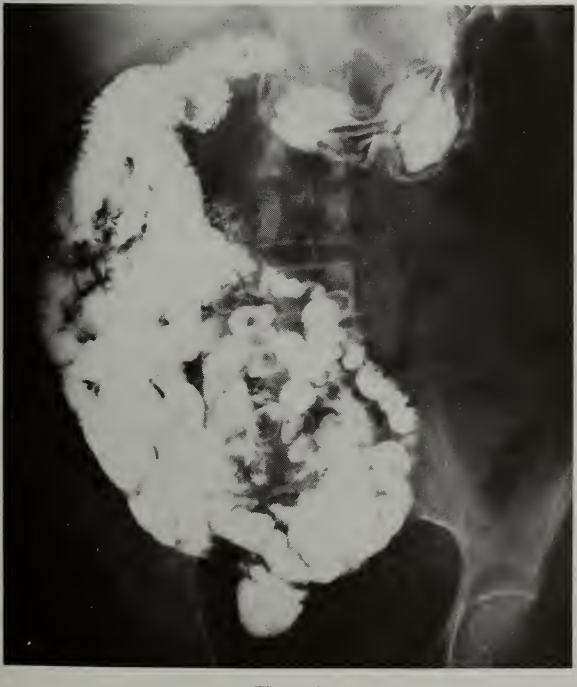

Figure 2
Midgut nonrotation.

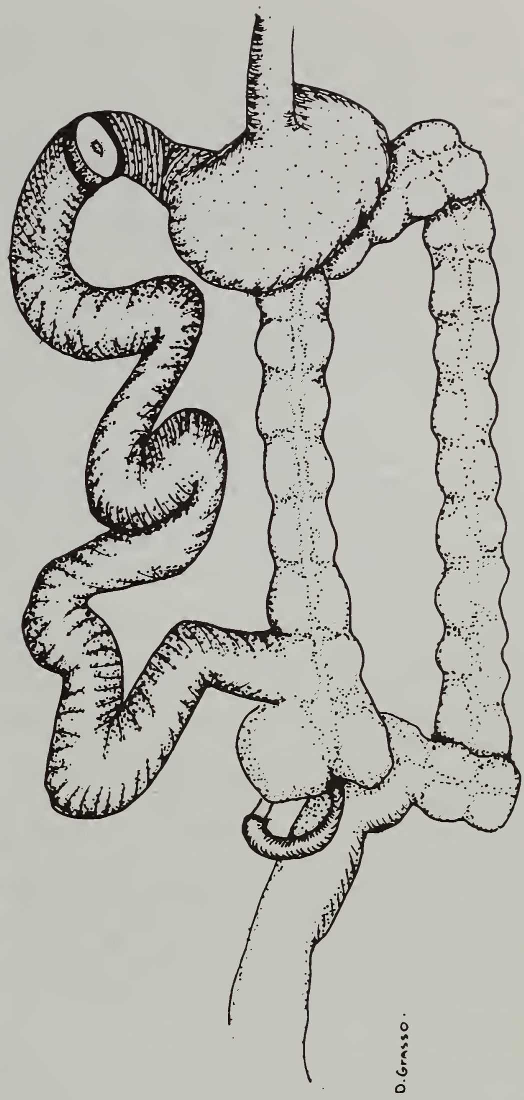

Figure 3
Schematic representation of findings at surgery.

Discussion

Symptomatic congenital gastrointestinal anomalies are uncommon in adults.[1-6] The association of two rare anomalies is indeed unusual.

Midgut nonrotation results from a failure of the first and second stage of midgut rotation occurring during the fifth to eleventh week of embryonic life. It occurs in approximately 0.2% of the adult population and is usually asymptomatic. In this anomaly, the duodenum descends to the right of the superior mesenteric artery and all the small gut is located in the right half of the abdomen. The terminal ileum enters the left-sided cecum by crossing the midline from the right. The transverse colon folds on itself to enter the normally placed hindgut. Adhesive bands may be present from the cecum to the duodenum.

Review of the literature reveals only a scant number of patients with symptoms related to midgut nonrotation.[1-3] Problems include a high incidence of peptic ulcer disease (presumed related to extrinsic partial outlet obstruction of the duodenum from congenital bands), acute bowel obstruction (usually with symptoms of abdominal pain for months and even years prior to the acute episode), and chronic abdominal pain relieved by surgical correction of the nonrotation (the Fitzgerald Procedure).[2]

Duodenal diaphragm is believed to result from the incomplete vacuolization of the duodenum. At 30 to 60 days of embryonic development, the entire duodenal lumen is occluded by a proliferating epithelium forming a solid core. Cystic spaces develop in this core and coalesce to establish a patent lumen. Failure of these vacuoles to completely coalesce may lead to an intrinsic cause of obstruction such as atresia, stenosis, or a diaphragm. A diaphragm occurs once in approximately every 20,000-40,000 births with less than 40 cases having been reported in adults.[4-7]

If the diaphragm causes only partial duodenal obstruction because of a relatively large sized aperture, symptoms may not develop or be minimal for years. In the adult, typically symptoms of epigastric fullness, nausea, vomiting and weight loss are usually insidiously progressive over years. Frequently, the condition will be misdiagnosed as peptic ulcer disease because of a misinterpreted duodenal deformity on Upper G.I. Series.[4] Excision of the diaphragm is the procedure of choice. This may be accomplished by fiberoptic endoscopy with mulitiple biopsies until the web is obliterated.[4] However, few diagnoses are made prior to surgery. Duodenotomy with excision of the diaphragm is the surgical procedure of choice.[6]

Conclusions

Congenital webs, nonrotation, and other gastrointestinal anomalies should be given due consideration regardless of rarity and patient age with any case of chronic gastrointestinal symptoms not responding to routine therapy.[6] The therapy of congenital anomalies in the adult can be quite simple if diagnosed preoperatively. Precise diagnosis avoids an operation of greater magnitude and morbidity.

The association of malrotation with intrinsic (atresia, stenosis, diaphragm) and extrinsic causes (annular pancreas, peritoneal bands, anterior portal vein, duplication of the duodenum) of duodenal obstruction have been reported in the neonate.[7] In Harvey's series of neonatal duodenal obstruction, there are 28 patients with a malrotation. Six of these 28 patients had an intrinsic cause of duodenal obstruction. They recommended a catheter be passed through the duodenum in all cases of malrotation with duodenal obstruction to rule out an intrinsic cause.[7]

Similarly, any adult with a malrotation of the gut with a clinical and radiologic diagnosis of peptic ulcer disease should undergo upper endoscopy prior to treatment to rule out congenital intrinsic duodenal pathology.

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Psychological Preparation for Elective Surgery

LEO GALLAND, M.D., F.A.C.P.

ABSTRACT—Several controlled studies have shown that brief instruction in behavioral techniques for reducing post-operative discomfort can decrease anxiety, pain and length of hospital stay. Giving patients detailed information about the nature of post-operative pain and care without teaching these coping techniques has variable results, increasing requests for pain medication in some patients. Pre-operative behavioral instruction can be effectively implemented with a small commitment of staff time.

Numerous investigators have attempted to influence short-term morbidity following major surgery by pre-operative psychological intervention; many have evaluated outcome using objective indicators such as length of hospital stay, amount of post-operative analgesia, occurrence of medical complications.[1-8] Three types of psychological preparation for surgery have been employed, usually in combination: 1. instructing patients in specific techniques for increasing activity while decreasing pain (e.g. proper body mechanics, leg exercises, proper use of a trapeze); 2. instructing patients in pain and anxiety reduction techniques such as distraction and muscle relaxation; 3. giving detailed, accurate information about the nature and reason for pre-operative procedures and the nature, severity and duration of post-operative discomforts (preparatory information). Pre-operative and intra-operative hypnotic suggestion has also been employed to reduce post-operative pain and discomfort.[9-11] As a group, these studies have shown significant reductions in post-operative morbidity for patients receiving psychological preparation.

In the largest study, 152 patients about to undergo abdominal surgery were instructed in deep breathing, leg exercises, and body mechanics and were given some preparatory information. Compared to a control group of 140 patients who did not receive this special instruction package, the experimental group left the hospital 3 to 4 days earlier, ended the use of parenteral and oral pain medication earlier, had fewer family members staying at the hospital overnight, and had a lower frequency of post-operative medical complications. There was one case of wound dehiscence and two cases of pneumonitis in the control group, compared to four cases of pneumonitis, five cases of paralytic ileus, and seven cases of thrombophlebitis in the control group. Whether patients actually used the specific techniques taught was not reported. Presumably patients utilized their instructions to reduce pain and increase activity. Possibly, just knowing there were active adaptations that could be made to the trauma of surgery reduced their anxiety, thereby lowering pain and increasing activity.

Two studies have established the value of anxiety-lowering techniques in reducing post-operative morbidity. Langer, Janis and Wolfer[4] taught a coping device to 30 surgical patients. The coping device employed cognitive reappraisal to help patients focus on the positive aspects of the surgery and was accompanied by the explicit suggestion that they could exert more control on their emotions and perceptions than they realized. The experimental group showed a significant reduction in pre-operative anxiety and in post-operative requests for pain medication compared to an attention control group. Wilson[8] studied the effect of presenting a 25-minute tape of instruction in systematic muscle relaxation to a group of patients, predominantly women, scheduled for abdominal hysterectomy or cholecystectomy. He does not report the patients' compliance with the use of relaxation although almost all patients rated the tapes as effective and expressed a desire for future use of similar tapes if they were hospitalized again. The group trained in relaxation had a shorter hospital stay (6 versus 7), less pain distress, and increased energy and sociability than a control group; they were more active and used less pain medication. Patients with high levels of pre-operative fear showed less benefit than patients with low levels of pre-operative fear, possibly because they needed more time to develop their coping skills. Wilson recommended that patients with high levels of fear be given relaxation training prior to hospital admission.

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The effects of preparatory information are quite complex. Wilson observed a decreased length of hospital stay but no changes in other measures of post-operative morbidity among patients in his study who received a 9-minute information tape instead of relaxation training. Andrew found that presenting preparatory information was associated with decreased length of stay *and* diminished medication use for men in a Veterans Hospital. Actually learning the information on the tape did not affect recovery. She concluded that hearing the tape served as an initial vicarious exposure to the stressful stimulus which allowed some patients to adapt beforehand to the psychological stress of surgery by a process of catharsis. This theory is consistent with Janis's observation that giving preparatory information alone increased pre-operative anxiety but decreased post-operative use of pain medication. Miller[13] reported that women undergoing colposcopy responded to 20 minutes of preparatory information with increased pre-operative anxiety and expectations of greater intra-operative pain than a control group. During the procedure, however, informed patients showed less crying-out and hand-clenching. Because informed patients complained of more pain and discomfort post-operatively than did controls, Miller doubted that informed patients were coping better with the stress of the procedure.

Individual differences among patients predict how they will respond to information. Andrew and Miller both observed that patients whose habitual coping style was characterized by avoidance of threatening emotions or distraction from threat-relevant information appeared to experience more pain or distress after receiving copious preparatory information. Wilson also identified a group that responded to information by requesting more pain medication and reporting more discomfort after surgery. These were patients who habitually reacted to stressors without showing overt anger or pain (repressors). The repressor tendency did not correlate well with a coping style of denial, so that repressors may not be the same as avoiders. Wilson theorized that repressors only *appeared* to be harmed by information. Information gave them permission to express pain and discomfort and request medication. That this effect was therapeutic and not harmful is suggested by two findings: repressors who received the information tape had a shorter length of stay than un-informed repressors, and all informed repressors expressed a desire for similar preparation during future hospitalization.

The available literature indicates that brief training in a variety of specific coping skills is a useful preparation for major surgery and reduces post-operative psychological and physical distress. These skills include progressive muscle relaxation, the use of distraction to minimize pain, and efficient use of body mechanics post-operatively. Giving patients detailed information about the nature of post-operative pain and discomfort tends to increase pre-operative distress, decreases intra-operative distress, and has variable effects on post-operative recovery which are related to the severity of the surgery and individual personality characteristics of patients. The addition of coping skills training to preparatory information eliminates the information-related increase in pre-operative anxiety,[4] and can produce beneficial effects that are greater than for either intervention alone.[14] Since taped[8] and audiovisual[12] instructions are of demonstrated value in decreasing post-operative pain and anxiety, behavioral preparation may be instituted with a relatively small commitment of nursing time.

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Advances in the Diagnosis and Management of Corneal Disease

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ABSTRACT—Recent advances in ophthalmologic diagnosis and therapy have brought an improved outlook in patients with corneal disease. The cornea, a thin, transparent membrane, serves both as a structural support for the anterior ocular segment and as the predominant refracting power to focus ambient light on the retina. As a result of trauma, inflammation, dystrophic change or surgical misadventure, the cornea may become edematous and cloudy, due to dysfunction of its endothelial cell layer. Using techniques of photodocumentation, standard and wide-field specular microscopy, pachymetry, and innovations in corneal transplantation, formerly blind eyes with poor visual prognosis can now be visually rehabilitated.

Recent advances in ophthalmology have improved the prognosis in patients with corneal diseases. Combining new diagnostic tests and techniques such as photodocumentation of the cornea by external and slit-lamp photomicrography, standard and wide-field specular microscopy of the corneal endothelium, and pachymetry, with therapeutic advances in long-term storage of corneal tissue, ultrafine monofilament nylon suture material, and corneal transplantation innovations, the ophthalmologist now has a formidable armamentarium with which to conquer formerly poor visual prognosis cases of corneal disease.

Anatomy of the Cornea

The cornea is a transparent membrane functioning as structural support to the anterior ocular segment and providing the major refractive optical surface of the eye, focusing light onto the retina. The cornea is 0.5mm thick, composed of epithelium, Bowman's layer, stroma, Descemet's membrane and endothelium (Figure 1). The epithelium is a barrier to various noxious agents such as chemicals, dust and bacteria. The stroma, composed of 150-200 collagen lamellae embedded in a mucopolysaccharide matrix, is arranged to allow the passage of light without diffraction. The posterior corneal surface, its endothelium, serves as a physiological pump, keeping the stroma and epithelium continuously deturgesced and clear. Should the endothelial pump fail, aqueous would be imbibed by the cornea, stromal lamellar separation would increase, and the cornea would become edematous and cloudy, with secondary pain and visual loss. The endothelial cell layer is, however, extremely fragile. Inflammation, trauma, dystrophic changes or surgical misadventure, during cataract and intraocular lens implant surgery especially, can cause damage of the endothelial cells, failure of the pump, and corneal edema.

Diagnostic Advances In Corneal Disease

The most important advance in corneal diagnosis is photodocumentation by external and slit-lamp photography. The slit beam enables the observer to identify a lesion's location and *depth* within the cornea (Figure 2 and 3).

New advances in specular microscopy have enabled ophthalmologists to photograph living human en-

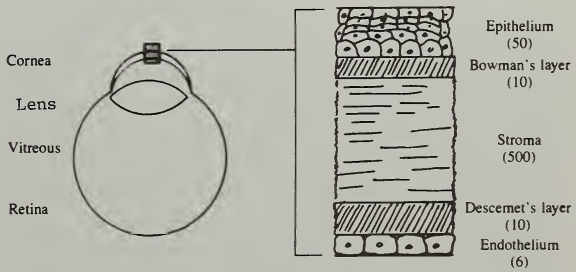

Figure 1

Anatomy of the cornea. The numbers in parentheses represent thickness in micra (10^{-6}m).

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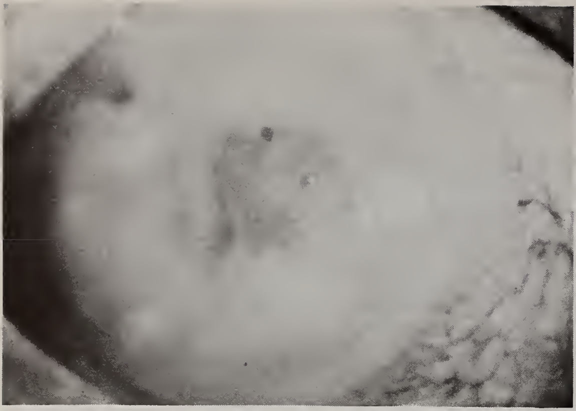

Figure 2

External photograph of a cornea with pseudophakic bullous keratopathy, corneal edema secondary to intraocular lens-induced damage to the endothelium.

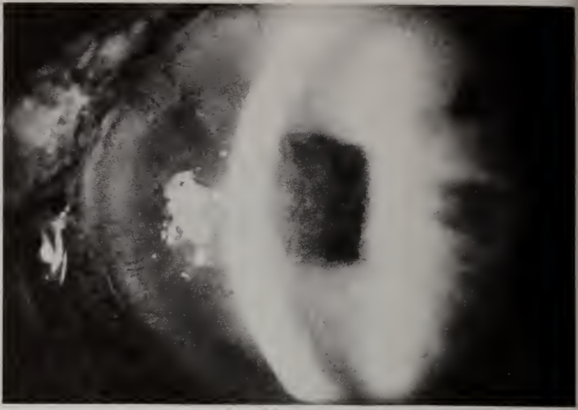

Figure 3

Slitlamp photograph of the same eye as Figure 2, after deturgescing the cornea with topical glycerin. The deep Descemet's membrane folds (striate keratopathy) are now readily visible.

dothelial cells. Standard field specular microscopy allows the observer to count up to 150 cells per field (Figure 4), but the newer wide-field specular microscopes enable a photograph of up to four times the area at once, allowing up to 2000 cells to be photographed at a time (Figure 5). Comparing Figures 4 and 5, there is noted an increase in area of wide-field specular microscopy (1mm^2) versus standard field specular microscopy (0.29mm^2).

Whereas specular microscopy gives a static figure of endothelial cell number, corneal pachymeters define corneal thickness, a *function* of its *physiology,* the endothelial pump. An increase in corneal thickness is associated with more light scattering and diffraction, corneal edema, pain and visual loss. Corneal pachymetry, then, gives the observer concrete evidence of endothelial cell viability; the thicker the cornea, the poorer the endothelial cell *function.*

Other instruments in the ophthalmologic armamentarium are the corneal esthesiometer, which measures corneal sensation; Goldmann applanation tonometer, which measures intraocular pressure; and the pneumotometer, which, too, measures intraocular pressure in scarred, diseased or transplanted corneas where Goldmann tonometry is inaccurate or impossible to perform.

New Advances in Corneal Therapeutics

One of the major surgical advances of the twentieth century has been the development of corneal transplantation. This procedure, termed penetrating keratoplasty (PK), is a technique by which donor cornea from an enucleated cadaver eye is sutured into the recipient bed of the host, obtained by removing the diseased cornea.

PK remains the most successful of all organ transplants, with over 90% of cases "taking" in the host. Since the cornea is an avascular tissue, the immune response, so apparent in kidney, heart liver and lung transplant, is less operative in corneal transplantation.

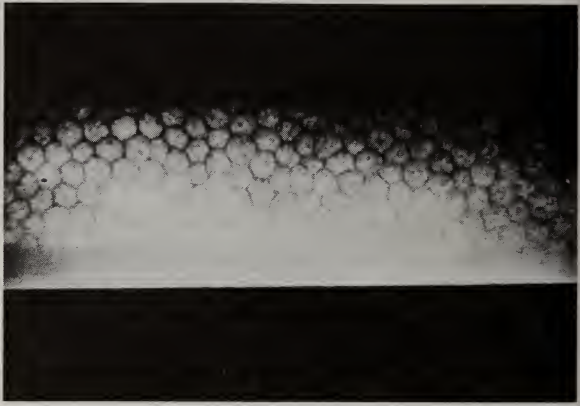

Figure 4

Standard field specular photomicrograph showing the normal quasihexagonal pattern of the endothelial cell mosaic. The total area photographed is 0.28mm^2.

Certainly, PKs performed in the setting of scarred, *vascularized* corneas (such as herpetic keratitis or alkali burns) are associated with a higher degree of graft rejection, because the blood vessels can bring sensitized T lymphocytes to the donor cornea, inciting a graft reaction or rejection.

There is now a method of preserving corneal donor tissue for longer periods of time than previously, using MK medium, a solution of dextran, culture medium 199 and gentamycin. A circumferential ring of donor cornea and surrounding sclera is excised from the enucleated eye, placed in MK medium and cooled to 4° C, where it can be maintained, transported and used up to 72 hours later. The death-to-MK preservation time is critical, optimally within six hours, to keep the fragile endothelial cells viable. Despite the use of gentamycin in the MK medium, several disastrous cases of donor sepsis have resulted from PK, in which microbial contaminants including rabies, Creutzfeldt-Jacob virus, Cryptococcus neoformans and flavobacterium have been cultured.

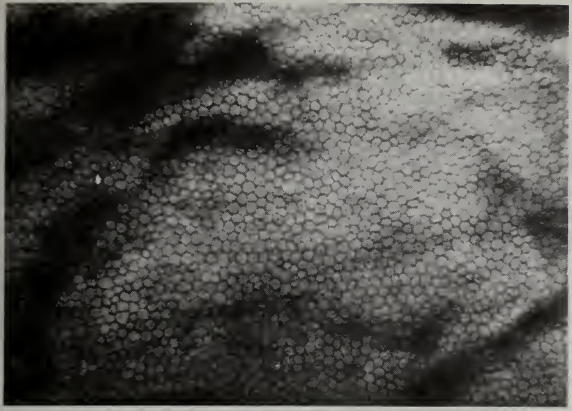

Figure 5

Wide-field specular photomicrograph showing normal quasihexagonal endothelial cell pattern. The total area photographed is quadrupled (area = 1.1mm^2).

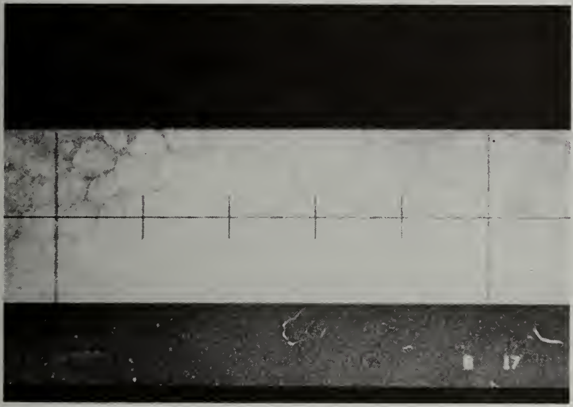

Figure 6

Standard field specular photomicrograph showing fewer endothelial cells, with bizarre, pleomorphic shapes, a sign of endothelial cell loss and dysfunction.

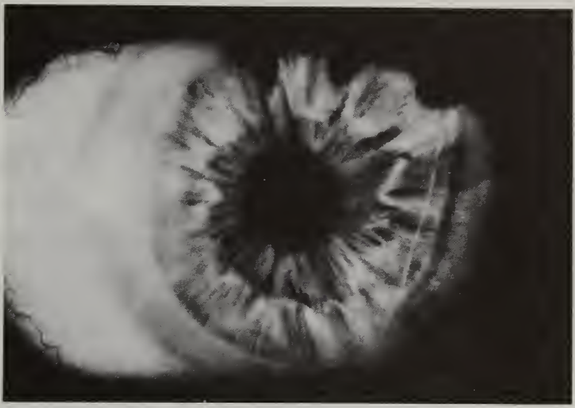

Figure 7

Successful corneal transplant (penetrating keratoplasty) in a patient with pseudophakic bullous keratopathy, demonstrating a crystal clear graft and anterior chamber intraocular lens.

The eye banks established in the United States and abroad handle corneal tissue and make it available to ophthalmic surgeons worldwide. It has been estimated that over 11,000 corneal transplants were performed in the United States in 1982, a steady increase from the 200 performed in 1960. With more available corneal tissue and better techniques of preservation, projections of 20,000 transplants a year in this country by 1990 are realistic.

The actual operation of PK is straightforward. The diseased host cornea is removed with a trephine and the donor cornea is sutured in its place. The patient may be operated upon under local or general anesthesia. A supportive Flieringa ring is sutured to the episclera of the host cornea and a corneal trephine, an exquisitely sharp "surgical cookie cutter," cuts the recipient cornea down to the level of Descemet's membrane at which point razor blade and then scissors remove the diseased tissue. Anterior segment reconstruction, removal of cataract, removal and/or insertion of an intraocular lens is carried out at this point depending on the surgical indication. Viscoelastic substitutes, such as sodium hyaluronate, are used to coat an intraocular lens and the donor cornea to protect the endothelium from trauma or touch by intarocular lens, iris or vitreous. Then, using either interrupted, continuous or a combination of sutures, the donor cornea is sutured into place.

The most common indication for PK in 1983 is pseudophakic bullous keratopathy (PBK), corneal edema as a result of intraocular lens implantation. Other major indications include chronic herpetic keratitis, keratoconus, Fuchs' endothelial dystrophy and regrafts. For PBK, the definitive surgical intervention is PK, often with removal of the offending intraocular lens, and, in some circumstances, replacement with a better tolerated intraocular lens affixed in the anterior chamber angle or sutured behind the iris.

The success of PK only begins with the operation and is contingent on the surgeon's technique, continual vigilance in the postoperative period, the patient's willingness to adhere to a strict regimen of topical and possibly systemic medication and the successful management of corneal graft rejection. Even if all of the above are accounted, a clear corneal graft can fail to provide excellent vision either because of pre-existent macular (retinal) edema, glaucoma, or significant corneal astigmatism.

Advances in the diagnosis of corneal disease using photographic, biomicroscopic, and pachymetric techniques have combined with such therapeutic modalities as long-term corneal preservation, the use of viscoelastic substitutes and monofilament nylon suture, to produce good anatomic results in patients with corneal disease. Preexistent macular edema, glaucoma and postkeratoplasty astigmatism may, at times, hinder the successful visual outcome of a perfectly executed procedure. Nevertheless, useful vision and reduction in pain and irritation, can now be achieved in the majority of patients as a result of these new techniques.

Evaluation and Treatment of Insomnia

ROBERT K. WATSON, PH.D. AND KARL-OTTO LIEBMANN, M.D., FAPA

> *Sleep that knits up the ravelled sleeve of care,*
> *The death of each day's life, sore labour's bath,*
> *Balm of hurt minds, great nature's second course,*
> *Chief nourisher in life's feast.*
>
> *–Macbeth II, ii, 53*

Far from being a simple state of rest and quiescence, sleep is an active and complex biological process. The delicate architecture of sleep is composed of distinct stages which recur in regular cycles.

Stage 1 sleep, the twilight zone between waking and sleep, is characterized by slow rolling eye movements and vertex sharp waves and theta activity in the EEG. The sleeper usually spends only a few minutes in this transient stage before descending into Stage 2 which is characterized by sleep spindles and K-complexes in the EEG. The sleeper then descends further into Stage 3 and 4, together called "delta sleep," characterized by high amplitude slow waves called delta waves. This is the deepest stage of sleep from which the sleeper is most difficult to arouse and may be the stage most necessary for physical restoration.

Following sleep deprivation, delta sleep is the stage of sleep made up first on following nights. Taken together Stages 1 through 4 are called nonREM or NREM sleep. Arising from delta sleep, the sleeper ascends into rapid eye movement (REM) sleep which is as distinct from NREM sleep as it is from waking. REM, the most dramatic stage of sleep, is characterized by an active low amplitude, fast frequency EEG. Full-blown dreams blossom out of REM sleep, and the eyes move as though the dreamer was the audience to his own dreams. There is a suppression of voluntary muscles which prevents the dreamer from acting out his dreams. Europeans call REM sleep "paradoxical sleep" because the brain is so active within a sleeping body. Many other physiological events occur during REM sleep; for example, there is a cycle of penile erections that coincides with REM sleep in healthy boys and men.

REM sleep normally occupies about 20% of sleep. The first REM period begins about 90 minutes after the beginning of sleep and the second REM period 90 minutes after that. Each REM period becomes longer so that most REM sleep is concentrated in the last part of the night. Delta sleep, in contrast, usually prevails in the first part of the night.

Far from being the dark empty room of the mind, lit only by occasional flashes of dreams, sleep is filled with nearly continuous mental activity which changes with the stages of sleep. The waking stream of consciousness becomes, during sleep, an underground river which usually passes unnoticed and unremembered. Vivid, bizarre, story-like dreams always accompany REM sleep. Even those people who claim they never dream will recall dreams in the laboratory when awakened from REM sleep. Of the 80 minutes a night spent in REM dreams, usually only fragments are recovered and most dreaming fades away as though it never happened. Even less likely to be recalled are the passing thoughts and ruminations and vague visual imagery that drift through NREM sleep or the hypnagogic hallucinations that appear on the edge of sleep. Mental activity during sleep, although usually unrecorded in memory, affects the quality of sleep.

The cyclic order of the stages of sleep and the amount of time in each stage is normally consistent and predictable, but altered in specific ways in association with specific sleep disorders.

Over the past few years, the new knowledge regarding the physiology and psychology of sleep has begun to be put to medical use in the evaluation and treatment of sleep and dream disorders.

Insomnia may be the most frequent medical complaint heard by physicians. According to the Institute of Medicine, each year about 10 million Americans consult a physician about their sleep.[1] Until recently, physicians had little to offer their sleepless patients except hypnotic medication. Sleeping pills may have their place

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in the treatment of certain types of transient insomnia, but their use beyond several weeks often causes more problems than cures. Physicians are increasingly aware that now they have other means of treating severe and persistent insomnia. Insomnia, like edema, fever, or abdominal pain, is a symptom with many possible underlying causes. Before insomnia can be effectively treated, it should be properly diagnosed.

The Association of Sleep Disorders Centers has drawn up a new *Diagnostic Classification of Sleep and Arousal Disorders.* [2] The second of the four sections of the new nosology classifies Disorders of Excessive Daytime Somnolence. Most of the patients in this second major category suffer either narcolepsy or sleep apnea. The third section covers Disorders of the Sleep-Wake Schedule, and the fourth section covers Parasomnias, such as sleep walking and nightmares. In the present review, we shall discuss only the first section on Disorders of Initiating and Maintaining Sleep (Insomnias). The nine diagnostic categories in that section and their treatment are described below:

1. Disorders of Initiating and Maintaining Sleep Associated with Persistent Psychophysiological Arousal

For many patients with persistent insomnia, going to bed is a distressing challenge, and they remain too aroused to allow themselves to fall asleep and stay asleep. Muscle tone remains high and heart rate undiminished. They may have difficulty suppressing the ruminations that run through their minds. Anticipating a sleepless night, they become anxious and lie in bed angry and tense. The more they struggle to sleep, the more they drive sleep away. Sleep is one of the few things in life that cannot be improved by trying harder. Since vague thoughts and ruminations can continue into sleep, these patients may actually drift in and out of sleep without being aware of it and later may subjectively underestimate the amount of sleep that they obtained. Often their insomnia began after a crisis or change in their lives such as the death of a friend, a serious accident, or promotion at work; but then, even after the crisis has passed, they continue to sleep poorly.

These patients can be best helped by relaxation training and stress management, perhaps aided by biofeedback, aimed at reducing their psychophysiological arousal. They can also be helped by learning the rules of good sleep hygiene. Some of these are: avoid the use of caffeine (coffee, tea and colas) in the afternoon and evening; maintain a regular sleep schedule by arising at the same time each morning, even on holidays and vacations; if sleep does not come, do not lie in bed feeling miserable, but get up and go into another room until sleepiness returns. L-tryptophan, a natural hypnotic, may be used to alleviate psychophysiological insomnia of mild to moderate severity. L-tryptophan, an amino acid, found in dairy products, meat, poultry, and tuna fish, is a precursor of serotonin, the neurotransmitter implicated in the induction of sleep. One to two grams of l-tryptophan administered between 30 to 45 minutes prior to bedtime is recommended. L-tryptophan is sold in 500 mg. tablets from health food stores, but may also be taken in a more tasty and less expensive form, such as a glass of milk and a tuna fish sandwich before bedtime.

2. Disorder of Initiating and Maintaining Sleep Associated with Psychiatric Disorder

Many psychiatric syndromes are accompanied by disturbed sleep. Trouble sleeping may present as the earliest symptom and one the patient most readily complains of without relating it to psychological problems out of shame, denial or plain lack of knowledge.

Depressive illness, characterized by loss of the capacity to experience pleasure, ideas of being worthless, helpless, and hopeless and by diminished appetite and sexual interest, is typically accompanied by difficulty falling asleep and frequent awakenings, the final one in the early morning hours.

The first stage of REM sleep normally begins about 90 minutes after the beginning of sleep. Most patients with primary depression or severe obsessive compulsive disorder show REM sleep beginning 30 to 50 minutes after sleep onset. This shortened REM latency is a biological marker of primary depression and contributes to the differential diagnosis of mood disorders.

Anxiety, including panic states, post traumatic stress disorders, obsessive compulsive neuroses and hypochondriasis also interfere with sleep. Psychotic patients often experience severe sleep onset insomnia or do not fall asleep at all as psychomotor agitation, delusions and frightening hallucinations pervade their nights and days. A manic patient can get up after two or three hours of sleep to resume his frantic pace with seemingly inexhaustible energy and no complaint of sleepiness or fatigue.

In each of these conditions, specific psychotropic medications combined with appropriate psychosocial therapies, rather than hypnotics, will bring about remissions or recovery. Unlike the insomnia associated with psychopsysiological arousal, poor sleep related to psychiatric illness improves as the illness improves.

3. Disorders of Initiating and Maintaining Sleep Associated with the Use of Drugs and Alcohol

Sleeping medication disrupts the delicate architecture of sleep, reducing deep (delta) sleep and fragmenting REM sleep. After a few weeks of use, sedative medication may become part of the problem because patients will not only have distorted sleep, but may not be sleeping any longer than when the sleeping pills were first prescribed. Furthermore, addiction may occur. When these patients attempt to discontinue the sleeping pills, their sleep is even worse. They assume that their worsened sleep is proof they need sleeping medications, not knowing that, in fact, it is a symptom of drug withdrawal.

The treatment for most of these patients is a gradual and carefully explained withdrawal and the reassurance that in time sleep will improve without medication. For some patients, supportive counseling may be indicated during the difficult and often lengthy period of their drug withdrawal.

For some people a glass or two of wine in the evening before bedtime may be a pleasant ritual. It should be understood, however, that no dose of alcohol will improve the quality of sleep. High doses of alcohol fracture and damage sleep so that for months even after total abstinence, the sleep EEG remains abnormal. The physician may wish to inquire whether an insomniac patient is medicating himself with alcohol.

4. Disorders of Initiating and Maintaining Sleep Associated with Sleep Induced Respiratory Impairment

Patients with obstructive sleep apnea repeatedly cease breathing during sleep as their upper airways collapse. Apneic events are ended only by brief arousals or awakenings which are usually not remembered by the patient. Severe sleep apnea, characterized by hundreds of apneic events, severe oxygen desaturation and cardiac arrythmias, is usually associated with the complaint of excessive daytime sleepiness. Milder or beginning forms of sleep apnea, however, are often associated with the complaint of difficulty maintaining sleep. Obstructive sleep apnea is 20 times more frequent in men than in women. It tends to develop in middle age and to worsen with time. Many men with obstructive sleep apnea are obese and most snore. The patient himself may be quite unaware that he stops breathing during sleep. His wife, however, may be able to describe brief periods when her husband's raucous snoring ceases and he does not appear to be breathing. In this case, as so often with sleep complaints, it is helpful to interview the spouse or bed partner since they observe the patient while he sleeps.

Mild to moderate sleep apnea is sometimes effectively treated by significant weight reduction. In some cases of obstructive sleep apnea, protriptyline (Vivactil) 10 - 60 mg. h.s. has proven to be helpful. Another non-invasive treatment is a "tongue retaining device" which, inserted in the mouth at bedtime, pulls the tongue and lower jaw slightly forward by negative pressure and thereby increases the size of the upper airway during sleep.

The awakening that terminates apneic events during sleep and restores breathing can be understood as a protective mechanism that prevents prolonged apneas. Any medication with sedative effects which increases the waking threshold is contraindicated in patients with obstructive sleep apnea since it will cause longer apneas, increased hypoxemia and more severe cardiac arrythmias.

5. Disorders of Initiating and Maintaining Sleep Associated with Sleep Related Nocturnal Myoclonus

A surprisingly frequent cause of difficulty maintaining sleep, particularly in older people, is "nocturnal myoclonus." These periodic movements of the lower legs, stereotypic contractions which last from two to five seconds, occur every 20 to 40 seconds, and cause EEG signs of arousal or complete awakenings. Nocturnal myoclonus may occur hundreds of times during the night and be the cause of multiple awakenings. The patient is not aware of these leg movements since they occur only during sleep; however, his bed partner may well be aware of being kicked from time to time during the night.

Nocturnal myoclonus is often effectively treated with clonazepam (Clonopin) 0.5 mg to 2.0 mg h.s. Regular use of clonazepam, as of all benzodiazepines, may lead to tolerance and the need for increasing doses which in turn causes drowsiness the following morning. Therefore, the intermittent use of clonazepam may be the most effective long term treatment of nocturnal myoclonus.

6. Disorders of Initiating and Maintaining Sleep Associtated with other Medical, Toxic or Environmental Conditions

Insomnia is often associated with certain CNS disorders, ulcer, gastro-esophageal reflux, uremia, infections, and chronic pain due to arthritis and other musculoskeletal disease. Noise, heat, humidity and cold may all interfere with restorative sleep. Treatment, of course, is directed at the underlying causes.

7. Disorder of Initiating and Maintaining Sleep Associated with Childhood Onset Insomnia

Patients falling into this category have suffered poor sleep since early childhood. Most of them show evidence of "soft neurological impairment" and have histories of hyperactivity, dyslexia or attention-deficit disorder. No effective treatment has been established for this relatively rare group of patients.

8. Disorders of Initiating and Maintaining Sleep Associated with Other Conditions

This category contains a number of diagnoses of which we will mention two. Difficulty maintaining sleep may in some patients be related to repeated interruptions of REM sleep. REM sleep normally occurs first about 90 minutes after sleep onset and then recurs in regular cycles every 90 or so minutes throughout sleep. Dreams and nightmares are generated during REM sleep. There are some patients who are so troubled by their bad dreams that they become conditioned to waking at the beginning of each REM period in order to avoid encountering their dreams.

Sometimes the complaint of poor sleep and waking tired and unrefreshed in the morning is associated with an atypical sleep EEG, characterized by the intrusion of high amplitude alpha activity into delta sleep. Many patients with "alpha-delta" sleep respond dramatically to low doses of amitriptyline (Elavil) 10-20 mg h.s.

As with the use of protriptyline for sleep apnea and clonazepam for nocturnal myoclonus, the use of amitriptyline for "alpha-delta" sleep is based on recent studies or clinical observations. The use of these drugs for the indications listed has not yet been included in the PDR.

9. No Abnormality

In this subcategory fall those patients who are naturally short sleepers, but believe they should be getting more sleep. The need for sleep varies considerably from person to person and, of course, the criteria for insomnia will also vary from person to person. Six hours of sleep may reflect severe insomnia in one person, but be plentiful sleep for another.

Also in this subcategory are those patients who honestly complain of poor sleep, but when studied in a laboratory show normal polysomnographic recordings, and thus, no objective findings. Probably, their complaints should be believed and the modest assumption be made that we are just beginning to learn about the biological causes of insomnia.

10. Insomnia Associated with Delayed Sleep-Phase Syndrome

This cause of insomnia is from the section on Disorders of the Sleep-Wake Schedule. We will comment on Delayed Sleep-Phase Syndrome here since it belongs in a discussion of insomnia. Some patients, particularly young people, come to the physician with the complaint that they take hours to fall asleep, although once asleep they sleep well and can sleep into the following day. Careful interview will reveal that these patients have allowed their biological clocks, their circadian rhythms, to run ahead of the time schedule of society. For instance, their biological clocks may be set so that their body is ready to go to sleep at 3 a.m. and to rise at noon. If they are forced to awaken by demands of school or work early in the morning, they feel miserable because their biological rhythms are set for sleep. They suffer sleepiness through the morning but then find that they become increasingly more alert as the day goes on. In the late evening, as most people in response to their "clocks" are winding down, these patients find themselves wide awake and alert.

People with delayed sleep phase syndrome can reset their biological clocks by forcing themselves to get up at one time, say 7 a.m., every morning including weekends and holidays. With perserverance, over a period of weeks, they will succeed in adjusting their circadian rhythms.

As can be seen in the preceeding review, some types of insomnia can be evaluated and treated in the physician's office. At other times, the physician may need the help of diagnostic services provided by a sleep disorders center. Connecticut's first Sleep Disorders Center, and the only one in Connecticut accredited by the Association of Sleep Disorders Centers, is located at the Griffin Hospital in Derby.

Over the past year, 1983, we evaluated a total of 142 patients at our Center, and, as a growing service, anticipate seeing close to 300 patients in 1984. Table 1 shows the distribution of patients into the major diagnostic categories. Not included in Table 1 are nocturnal penile tumescence studies done in our Laboratory for evaluation of sexual dysfunction.

Table 1

MAJOR DIAGNOSTIC CATEGORIES OF PATIENTS EVALUATED AT THE GRIFFIN HOSPITAL SLEEP DISORDERS CENTER – 1983

Major Category	*Number of Patients*	*Percentage*
Disorders of Initiating and Maintaining Sleep (Insomnia)	54	43.5%
Disorders of Excessive Somnolence	55	44.4%
Disorders of the Sleep-Wake Schedule	5	4.0%
Parasomnias (Night terrors, sleep walking, sleep paralysis, enuresis, etc.)	10	8.1%

The diagnoses of patients coming to our Center in 1983 with the complaint of insomnia are shown in Table 2. Multiple diagnoses are encouraged, but only the primary diagnoses of these patients are listed in the Table below.

Table 2

PRIMARY DIAGNOSIS OF PATIENTS WITH THE COMPLAINT OF INSOMNIA SEEN AT THE SLEEP DISORDERS CENTER IN 1983

Primary Diagnosis	Number of *Insomnia Patients*	
1. Insomnia associated with psychophysiological arousal	14	(23.7%)
2. Insomnia associated with psychiatric disorder (depression anxiety disorder, etc.)	16	(27.1%)
3. Insomnia associated with sedative abuse	6	(10.2%)
4. Insomnia associated with sleep induced respiratory impairment (Sleep Apnea)	3	(5.1%)
5. Insomnia associated with nocturnal myoclonus	4	(6.8%)
6. Insomnia associated with other medical, toxic or environmental conditions (chronic pain, drug toxicity, gastroesophageal reflux)	5	(8.5%)
7. Childhood-onset insomnia	1	(1.8%)
8. Insomnia associated with other conditions ("alpha-delta" sleep)	4	(6.8%)
9. No objective finding	1	(1.8%)
10. Disorder of sleep-wake schedule (delayed sleep-phase syndrome	5	(8.5%)

At the Sleep Disorders Center we begin by interviewing the patient and obtaining a careful history. As indicated, patients sleep one or two nights in our Laboratory where their EEG, eye movements, EMG from various muscle groups of the body, oral nasal airflow, respiratory effort, arterial oxygen saturation as measured by ear oximetry, and EKG are continuously recorded during sleep. Consultants in neurology, pulmonary medicine, otolaryngology, sexual dysfunction and cardiology are available as needed. Evaluations result in specific diagnoses with specific recommendations for treatment including drug therapy when indicated. We see ourselves primarily as a diagnostic service and treatment remains in the hands of the referring physician. If requested by the referring physician, we or our consultants in some cases carry out the treatment.

The Sleep Disorders Center itself is located in a house across the street from the Griffin Hospital that provides a quiet and privacy that would be difficult to find on a medical floor. On the second floor of the house patients sleep in bedrooms that are connected to the control room downstairs by cables, intercoms and closed-circuit TV. Most insurance carriers cover polysomnographic evaluations.

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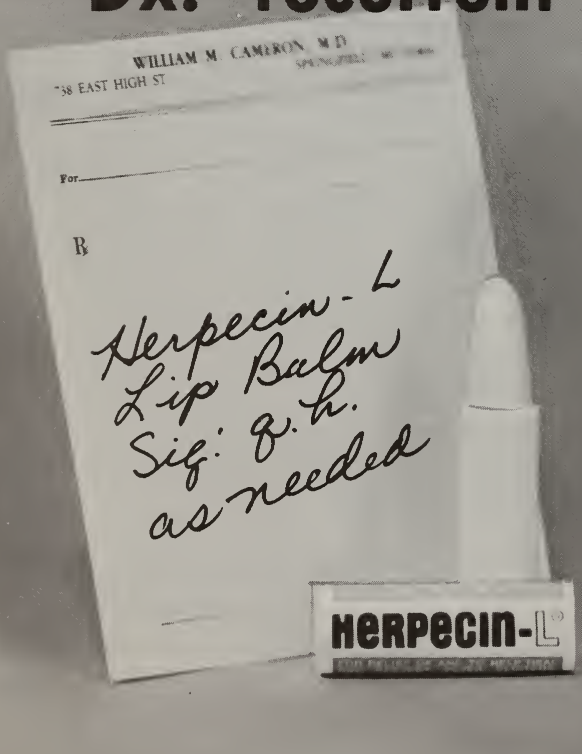
Dx: recurrent herpes labialis



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Important Advances in Clinical Medicine

Epitomes of Progress—Chest Diseases

The Scientific Board of the California Medical Association presents the following inventory of items of progress in chest diseases. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in chest diseases that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Chest Diseases of the California Medical Association and the summaries were prepared under its direction.

Strange Causes of Asthma

The reversible airways obstruction of asthma can be induced by a large number of well-known provocative factors. These include exposure to familiar inhalant allergens, chemical or physical irritants, cold air, exercise, viral respiratory tract infection, emotional factors and, less commonly, dietary ingestion of food allergens. In some patients, intermittent soiling of the tracheobronchial tree by aspirated gastroesophageal contents can be an important cause of exacerbation of asthma. Not infrequently, attacks of asthma occur "out of the blue," with no apparent precipitant. Chronic cough can be a major (or the only) symptom of asthma, which, though not necessarily associated with reversible bronchospasm, can be documented by evidence of airways hyperractivity when a patient is tested with certain inhalants ("cough-variant asthma"). Rarely, asthma may be mimicked by paroxysmal glottic obstruction that can be self-induced ("factitious asthma") or functional. Occasionally, true asthma may be provoked by strange or unusual causes that could escape the notice of patients and physicians unfamiliar with their asthmogenic potential. Some of these unusual or unsuspected causes of asthma include food additives, alcoholic beverages, certain drugs, iodinated radiographic contrast material, hemodialysis (due to acetate dialysate or complement-activation by cuprophane), domestic exposure to ureaformaldehyde foam insulation and a variety of occupational exposures (see below).

Food additives implicated in asthma include tartrazine dye, monosodium glutamate ("Chinese-restaurant asthma") and bisulfite preservatives, particularly when used in relatively high concentration as in restaurant foods, dried apricots or the processing of beer and wine; sulfur dioxide (SO_2) generated by the reaction of these sulfites with water provokes bronchospasm in some patients. Alcoholic beverages can induce bronchospasm due to adulterants in the beverage or, rarely, the ethanol itself. Commonly used drugs that can provoke asthma include aspirin and nonsteroidal anti-inflammatory agents; β-adrenergic antagonists (including timolol eye drops); drugs containing tartrazine (FD&C yellow No. 5) colorant additive; aqueous solutions of isoproterenol, isoetharine and metaproterenol containing metabisulfite preservative (from which liberated SO_2 could lead to "paradoxical bronchospasm"), and pancuronium bromide. Patients with asthma who have aspirin intolerance should be provided a list (available on request from the author, D. P. Tashkin, MD, Dept of Medicine, Center for the Health Sciences, UCLA School of Medicine, Los Angeles, CA 90024) of the more than 200 prescription and proprietary compounds that contain aspirin, most of which are combination products.

The prevalence of occupational asthma has risen dramatically in recent years due to the expanding list of asthmogenic substances used or generated in industry. In addition to gaseous irritants, animal proteins, grains, flour, gum, woods, drugs and enzymes, these substances include a number of low-molecular-weight compounds that may act as haptenes to produce immunologically

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mediated asthma: reactive dyes (including methyl blue in electrocardiographic ink); ethylenediamine (shellac, photographic chemicals); phthalic anhydride (paint, epoxy resins, meat wrapping); abietic acid (solder flux fumes leading to "colophony-induced asthma" in electronics workers); toluene diisocyanate (polyurethane foam, varnish), and other isocyanates (automobile spray paint, laminates). Physicians need to be alert to the possibility that "strange" causes of asthma may lurk in increasingly complex workplaces.

Donald P. Tashkin, M.D.

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Bronchoscopy and Lasers

Fluorescence bronchoscopy is a sensitive method to locate small mucosal or intrabronchial cancer lesions not found on routine bronchoscopy in patients with positive sputum cytology studies and normal findings on chest x-ray films. Diagnosis is warranted at this early stage (stage 0, or $T_{IS}N_0M_0$) because resection may be expected to be 90% to 100% curative. With this method hematoporphyrin derivative, which is retained within cancer cells (of all histologic types, primary or metastatic), is injected intravenously. The fluorescence bronchoscope uses violet light (410 nm) from a krypton ion laser, conducted via a fine quartz fiber (0.4 nm) in its suction channel, to its tip. Fluorescing lesions are visualized with an image intensifier, are then brushed and a forceps biopsy done for specific diagnosis.

Photoradiation therapy for endobronchial tumors by bronchoscopy uses the photodynamic action of hematoporphyrin derivative within tumor cells to produce singlet oxygen when activated by red light (630 nm) conducted via a quartz fiber from an argon-pumped dye laser. Power is low (200 mW), and there is no immediate visible change or coagulating effect. Cell and cell membrane function are gradually impaired so that tumor cells die over the next 24 to 48 hours. Tumor debris is then removed by repeat-bronchoscopy, to open up the bronchus to its full extent. Even a totally occluded bronchus can be fully opened up, and an atelectatic lung, lobe or segment may be re-aerated. Methods of light application developed are effective and efficient; generally (80% to 90% of cases) only one treatment is required. There have been no complications during photoradiation treatment of obstructing endobronchial tumors. Photoradiation therapy for early bronchial cancer is potentially curative, and clinical trials are under way.

Photocoagulation therapy uses pulses of a beam of intense (20 to 40 W) infrared light (1,060 nm) from an Nd-YAG laser. Tumor tissue is thereby immediately coagulated by heating (50° C to 60° C), or can be vaporized (100° C) by higher power (40 to 90 W). Large obstructing tracheal and main bronchus tumors after coagulation can be sheared off by the tip of the rigid bronchoscope. Tumors and granulation tissue masses and fibrotic stenotic areas caused by an endotracheal tube or tracheostomy can be vaporized. The tip of the fiber must be carefully aimed to prevent penetration of the wall, hemorrhage and possible death.

These new advances in bronchoscopic laser therapy are effective and safe in experienced hands. Still to be documented are patient benefits in terms of survival, the duration of control of the tracheobronchial lesions and whether they recur, the degree of improved breathing and lessened cough and the prevention of recurrent respiratory tract infections and distal pneumonia.

Oscar J. Balchum, M.D.

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Drug Therapy for Pulmonary Hypertension

The treatment of pulmonary hypertension depends on its cause and includes such diverse measures as anticoagulant or fibrinolytic therapy for pulmonary embolic disease; oxygen, bronchodilators and pulmonary hygiene for patients with chronic obstructive pulmonary disease, and surgical treatment for patients with congenital heart disease and mitral stenosis. There is some evidence that the use of the bronchodilator terbutaline sulfate may decrease pulmonary vascular resistance and lessen the load of the right ventricle in patients with chronic obstructive pulmonary disease.

A variety of vasodilator drugs have been used with varying success in the treatment of primary pulmonary hypertension and other forms of pulmonary hypertension. These include tolazoline hydrochloride (25 mg every four to six hours), isoproterenol hydrochloride (10 to 20 mg sublingually every three to four hours), hydralazine hydrochloride (25 to 75 mg every six hours), diazoxide (100 to 200 mg every 8 to 12 hours) and, most recently, nifedipine (10 to 40 mg every six hours). Individual patient response is influenced by the summation of pharmacologic effects on the systemic and pulmonary circulations. These vary from person to person. Vasodilators may reduce pulmonary vascular resistance and pulmonary artery pressure may not change if the cardiac output increases as the pulmonary vascular resistance falls.

Alternatively, pulmonary artery pressure may increase in patients in whom systemic effects predominate, resulting in a fall in systemic vascular resistance and increased cardiac output without a simultaneous fall in pulmonary vascular resistance. Initiation of therapy for primary pulmonary hypertension requires heart catheterization and the careful hemodynamic assessment of individual patient response to specific drugs.

Total heart-lung transplantation has been successfully completed in victims of primary pulmonary hypertension and is an experimental form of treatment that holds promise.

To develop a better understanding of the natural history, pathophysiology and response to therapy of primary pulmonary hypertension, a national registry of cases and a cooperative, multicenter study group has been established. Information regarding referral of patients into the study may be obtained by writing to Primary Pulmonary Hypertension Registry, c/o Chief, Interstitial Lung Disease Branch, Division of Lung Diseases, National Heart, Lung and Blood Institute, Westwood Bldg, 6A03, 5333 Westbard Avenue, Bethesda, MD 20205.

Philip M. Gold, M.D.

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Staging of Lung Cancer

In view of variations in published survivorship data for patients with lung cancer with regional nodal involvement—that is, hilar-mediastinal—advances in prethoracotomy diagnostic techniques and the lack of uniformly accepted anatomic definitions of each regional-pulmonary nodal station, the American Thoracic Society formed a committee on lung cancer and charged it to:

- Develop a map of regional pulmonary lymph nodes that would be acceptable to all physicians who care for patients with lung cancer.
- Develop multifactorial criteria for the extent, degree and type of nodal involvement in cases of primary lung cancer.

The recommendations of this committee, with respect to these two charges, were recently published. A map of regional pulmonary nodes was presented and the anatomic definitions of each nodal station were tabulated. It was recommended that this mapping technique be adopted to ensure uniformity in recording and publishing patient data. Only then can surgical series be compared and the impact on five-year survival determined. Such prospective data may allow clearer definition in the future of the criteria for surgical resection.

Gennaro M. Tisi, M.D.

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Nonsurgical Treatments for Sleep Apnea Syndromes

Sleep apnea syndromes involve a complex of manifestations that often interact progressively, threatening a patient's comfort, functioning and occasionally life. Such features include sleep fragmentation, autonomic nervous system stimulation, cardiovascular changes and pulmonary dysfunction. A thorough medical evaluation, including imaging of the upper airway, is necessary to determine the efficacy of treatment, the evaluation being directed at part or all of such perturbations, carefully defining the importance of local anatomic abnormalities and of central or effector system impairment.

Approaches to managing sleep apnea syndromes have included surgical and mechanical corrections (not considered in this article), oxygen therapy, weight reduction where appropriate and the use of a variety of medications. Evaluation has been applied to at least the following medicines.

- Clomipramine hydrochloride,
- Protriptyline hydrochloride,
- Medroxyprogesterone acetate,
- Acetazolamide,
- L-Tryptophan,
- Theophylline ethylenediamine (aminophylline),
- Naloxone hydrochloride,
- Bromocriptine mesylate,
- Strychnine,
- Almitrine.

Conclusions concerning efficacy may be broadly divided into those with predominantly central (or diaphragmatic) or predominantly obstructive causes.

1. No one has reported that drugs alone have completely resolved a severe obstructive or central syndrome in which apnea is continuous and associated with significant repetitive oxygen desaturation during sleep.

2. Weight loss alone in obese persons has led to the disappearance of a predominantly central or a predominantly obstructive sleep apnea syndrome in specific, selected cases. Low-flow oxygen given during sleep in conjunction with weight loss, again in selected cases, particularly in predominantly central or mixed syndromes, has helped to halt significant oxygen desaturation during the weight loss period.

3. Some drugs have essentially no effect, such as bromocriptine (given for obstructive apnea), naloxone (for obstructive apnea; reports conflict regarding predominantly central problems but even in these cases most results are negative) and almitrine (for obstructive apnea).

4. Other drugs have been beneficial *in certain cases.* Aminophylline has been helpful in treating central apnea associated with cardiac failure. (In only one article is central apnea clearly distinguished from the Cheyne-Stokes breathing pattern, which is also alleviated by aminophylline). Strychnine has been reported effective in non-rapid-eye-movement (NREM) sleep apnea, but it has only been tried in three patients. Acetazolamide is helpful in treating central sleep apnea at high altitudes, but its efficacy in cases of central apnea at sea level is questioned. L-Tryptophan, which also affects sleep, has been helpful when taken in 3- to 5-gram doses before bedtime in mild or moderate central and mixed apnea syndrome, particularly in the elderly. The tricyclic medications (initially clomipramine, more recently protriptyline) have been reported effective in mild to moderate central, mixed and obstructive syndromes since 1970. Presently protriptyline, 10 to 20 mg, is most commonly prescribed to be taken at bedtime. It affects muscle tone and rapid-eye-movement (REM) sleep, but the well-known tricyclic antidepressant side effects, particularly in the elderly, and the need to take the drug for a long period have limited its prescription. Similarly, medroxyprogesterone given in selected cases of predominantly central or mixed sleep apnea syndrome has proved efficacious, probably because of its effect on central respiratory drive and its diuretic effect. It also helps obese patients who have a combination of obesity-hypoventilation syndrome during sleep and heavy snoring with obstructive hypopnea. The prescribed daily dosage varies between 60 and 150 mg.

In conclusion, medical treatment may be effective for mild to moderately severe sleep apnea syndromes, particularly if imaging does not indicate a significant narrowing of the oropharyngeal airway during the awake state and if a patient is not excessively obese. A combination of treatments can be considered after a complete investigation. The most common are weight loss with or without low-flow oxygen and medroxygesterone, weight loss with or without low-flow oxygen and protriptyline (less frequently prescribed because of the eventual increase in appetite with protriptyline) and L-tryptophan and low-flow oxygen.

Christian Guilleminault, M.D.

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Guilleminault C, Cummiskey J, Dement WC: Sleep apnea syndrome: Recent advances. Adv Intern Med 26:347-372, 1980.

Adverse Drug Interactions With Theophylline

Several drugs can increase the activity of the hepatic cytochrome P-450 system, resulting in a more rapid elimination of theophylline. The serum level of theophylline may thereby be decreased, and inadequate control of bronchospasm can be expected. The dosage requirements of theophylline may be almost doubled with heavy smoking of marijuana or cigarettes and a return to normal may gradually occur over many weeks after smoking cessation. Other drugs that clearly increase theophylline elimination are phenytoin, which may reduce the serum theophylline level by 75% if given for ten days, and phenobarbital, which has less effect. A diet high in charbroiled protein or where there is a significant reduction in coffee intake can cause an increase in the rate of theophylline excretion. In contrast, theophylline use may cause a reduction in the serum concentration of phenytoin or lithium when given with either of these drugs, and their dosages may need to be increased.

Drugs that impair hepatic excretion of theophylline include cimetidine, troleandomycin, erythromycin, allopurinol (when given in a dose of 600 mg a day for at least two weeks) and possibly propranolol hydrochloride. Only cimetidine and troleandomycin are of major concern as theophylline serum concentrations can be doubled by using these drugs, thereby resulting in the possibility of severe theophylline toxicity. Erythromycin can cause less of an effect, but clinical vigilance should be heightened when giving this antibiotic concurrently.

Irwin Ziment, M.D.

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Current Treatment of Pulmonary Tuberculosis

In the treatment of pulmonary tuberculosis, isoniazid in combination with ethambutol is successful in 95% of patients who complete 18 to 24 months of chemotherapy. Although these statistics are excellent, actual results achieved have fallen short of this ideal.

The major reason for treatment failure is related to neither the organisms nor the drugs but rather to lack of patient compliance. It has been shown that about 25% of patients do not complete 18 months of therapy. This frequency of premature termination of treatment, among other reasons, stimulated research into shorter courses of chemotherapy. Before the advent of rifampin, however, all attempts to shorten the duration of chemotherapy for tuberculosis resulted in unacceptably high relapse rates.

The bacteriologic basis of chemotherapy for tuberculosis is best understood by considering two populations of organisms: a rapidly dividing group of extracellular organisms and a more slowly growing pool in solid caseous material and within macrophages. Chemotherapy must be prolonged to effectively sterilize this latter pool of "persisting" organisms. Rifampin seems to be uniquely effective against this population of slow or intermittently active organisms, as shown in simulated conditions of intermittent growth in vitro. Field trials in many parts of the world have demonstrated the efficacy of 9- to 12-month regimens containing isoniazid and rifampin, with reported relapse rates of less than 5%.

Isoniazid (10 mg per kg of body weight to a maximum dose of 300 mg a day) taken orally, plus rifampin (10 mg per kg to a maximum dose of 600 mg a day) taken by mouth daily for 9 to 12 months, and for a minimum of 6 months after proved bacteriologic sputum conversion, are now recommended for initial treatment of persons with uncomplicated pulmonary tuberculosis due to drug-susceptible organisms. For persons in whom there is suspicion that the disease is caused by isoniazid-resistant organisms (such as those who have immigrated from an area of high prevalence of primary isoniazid resistance), it is necessary to begin therapy with three drugs, adding ethambutol (15 mg per kg), until results of drug susceptibility tests are available. Except for patients with renal insufficiency, ethambutol adds little to the toxicity of the regimen and offers a safeguard against the possible development of resistance to both isoniazid and rifampin. If susceptibility to all drugs is shown, ethambutol may then be discontinued. At present, short-course chemotherapy cannot be recommended for tuberculosis caused by drug-resistant organisms. If supervision can be insured, then the isoniazid-rifampin regimen may be modified without loss of efficacy by administering the drugs daily for one to two months, then twice a week for seven to eight months. When given twice a week, the isoniazid dosage should be 15 mg per kg and rifampin, 10 mg per kg, to maximum doses of 600 mg.

With the use of isoniazid and rifampin, 90% to 95% of patients can be expected to have negative sputum cultures after three months of therapy. Bacteriologic evaluation should be done at this three-month jucture to determine if conversion has occurred. Persistently positive sputum cultures may suggest poor compliance or drug resistance. In some patients who have extensive disease, sputum conversion may take longer. Therapy may be stopped six months after sputum conversion, though it may be wise to continue for longer periods if there is continuing radiographic resolution.

Although there is no definite evidence for an increased risk of hepatotoxic effects with this regimen, some authorities recommend that it not be used in persons with acute hepatitis or severe underlying liver disease. Alcohol ingestion should be discouraged but is not a contraindication to using isoniazid and rifampin.

To date, there is little information on the use of rifampin in children, but preliminary data suggest that the nine-month isoniazid and rifampin regimen is equally efficacious and nontoxic if the previously described doses are used. Toxic effects on the liver appear to be more common with rifampin doses of 15 mg per kg of body weight or more.

Finally, although relapse rates have been remarkably low (1% to 4%), short-course therapy is still new and long-term follow-up data are not available. Until more information becomes available, patients should continue to be evaluated for 12 months after discontinuance of therapy. A review of symptoms, a chest roentgenogram and bacteriologic examination of sputum at 6 and 12 months should suffice to document a successful outcome.

Gary Slutkin, M.D.

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Invasive Diagnostic Approaches to Pulmonary Infiltrates

Patients can present with focal or diffuse pulmonary infiltrates as a manifestation of either specific pulmonary or general systemic disease. Infiltrates can appear patchy, nodular or dense. The most common causes of pulmonary infiltrates are acute infection, tumor and the many disorders that cause chronic diffuse infiltrative lung disease. In essence, findings on a chest roentgenogram are almost always nonspecific and the initial diagnosis depends on the clinical setting, results of laboratory tests (cultures and cytologic and serologic tests) or the response to empiric therapy. The great majority of patients with pulmonary infiltrates have straightforward infectious pneumonia or their disorder is diagnosed by other (noninvasive) tests.

Patients in whom an invasive diagnostic approach may be necessary include those with possible infectious disease who are unresponsive to empiric therapy after a reasonable period of time (days to weeks); immunocompromised patients (including those with the acquired immune deficiency syndrome [AIDS]) with suspected pulmonary infection of unknown cause; those in whom there is a high probability of neoplasm, and patients who have chronic diffuse infiltrative lung disease. Invasive diagnostic pulmonary procedures are appropriate only when there is the expectation that the findings may significantly alter treatment plans.

Three primary ways to obtain a pulmonary tissue specimen are percutaneous needle aspiration biopsy, fiberoptic bronchoscopy and open-lung biopsy. Trephine and needle core biopsy are less useful because of increased complication rates.

The choice of technique depends on four factors, the first being the type of specimen desired and the quality and location of the infiltrate. A percutaneous needle aspiration biopsy produces a cytologic specimen with insufficient tissue to show histopathologic architecture. (Newer aspirating needles may produce useable tissue.) It is an excellent technique for diagnosing infection or neoplasm in peripheral nodules. For diffuse infiltrates wherein infection is suspected the procedure can be done at the bedside without fluoroscopy. Obviously, chronic diffuse infiltrative lung disease cannot be diagnosed by this technique. Fiberoptic bronchoscopy using a Bartlett catheter can provide accurate bacterial diagnosis (aerobic and anaerobic) of lower respiratory tract infections. Bronchoalveolar lavage is remarkably productive in diagnosing infection and is currently the technique of choice in diagnosing *Pneumocystis* pneumonia in patients with AIDS (80% to 90% yield). Transbronchial biopsy can diagnose sarcoidosis in 60% to 85% of patients but is less effective for diagnosing chronic diffuse infiltrative lung disease (35% to 40%). A transbronchial biopsy in an immunocompromised host with pulmonary infiltrates of unknown cause provides a specific diagnosis in only 25% to 30% of patients. Open-lung biopsy is the gold standard: A large piece of tissue can be obtained for culture and histopathologic examination and the surgeon has an opportunity to grossly examine part of the lung. Not all areas are sampled, however, and the results are often nonspecific (5% to 10%), especially in immunocompromised patients with diffuse pulmonary infiltrates (45%).

Second, the choice of technique is greatly affected by the tempo of disease or of patient deterioration. If the process is explosive or a patient is regressing into respiratory failure, open-lung biopsy is often the *initial* procedure of choice. Such situations encourage earlier attempts at diagnosis.

Third, risks must be considered. Percutaneous needle aspiration biopsy has an associated death rate of about 0.1%. In 25% of patients a pneumothorax develops and 25% to 50% of these require a thoracostomy tube. Fiberoptic bronchoscopy with transbronchial biopsy has an overall death rate of 0.1% to 0.2%. Pneumothorax occurs in 5% to 10% of patients. Brisk bleeding is uncommon. Open-lung biopsy in cases of chronic diffuse infiltrative lung disease has a mortality of 1% to 2%. This procedure requires general anesthesia.

Finally, the choice of the invasive diagnostic approach depends on the skill of the physician doing the procedure. Clearly, a lack of familiarity with the technique increases the risk to a patient and may impede the securing of diagnostic material.

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Management of Childhood Asthma

Asthma in childhood originates from a variety of intrinsic and acquired factors that cause bronchial hyperreactivity and impair airways clearance on a chronic, recurrent basis. Respiratory tract disease or injury in early infancy may result in this syndrome, which can persist into adulthood as recurrent bronchospasm or permanent loss of elastic recoil with chronic emphysematous changes.

Although asthma clinically exhibits a continuum of respiratory impairment, newer therapies are directed toward both the acute and chronic states of the syndrome.

Status asthmaticus is a medical emergency. The basic principles of treatment are unchanged and include correction of hypoxemia, adequate hydration and treatment of the underlying infection. While repeated epinephrine injections have been the mainstay of emergency bronchodilator therapy, more recent evidence supports the equal efficacy of inhaled long-acting β_2-adrenergic agents such as albuterol and fenoterol. A greater degree of broncholilation, longer duration and less adverse reactions represent clear advantages of these agents. Continuous intravenous administration of theophylline ethylenediamine (aminophylline; dosage range, 0.65 to 0.85 mg per kg of body weight an hour, validated by serum concentrations of 10 to 20 μg per ml), corticosteroid infusion and, on occasion, intravenously given isoproterenol have reduced the need for assisted ventilation and the mortality in childhood status asthmaticus.

Much effort has been put into the management of chronic asthma in children. Optimal management reduces impairment, promotes growth and reduces the incidence of life-threatening episodes of respiratory failure. Theophylline given by mouth remains the principal medication indicated in maintenance therapy. Blood theophylline analysis by high performance liquid chromatography (HPLC) allows titration of dosages to suit individual patients. Compliance and continual efficacy are improved with the use of sustained-release tablets and granules that are better absorbed, enhance bronchodilation and increase palatability on a 12-hour (versus 4-to 6-hour) schedule. Inhaled β_2 agents (via portable nebulizer for young children or hand-held metered-dose devices for older children) are helpful supplemental therapies. The long-acting agonists are particularly important in this context, providing sustained bronchodilation with little rebound bronchospasm. Oral β-agonists may be used but are less desirable because of the adverse effects. Short-course corticosteroid administration has been shown to abort impending status asthmaticus with little impact on adrenal function.

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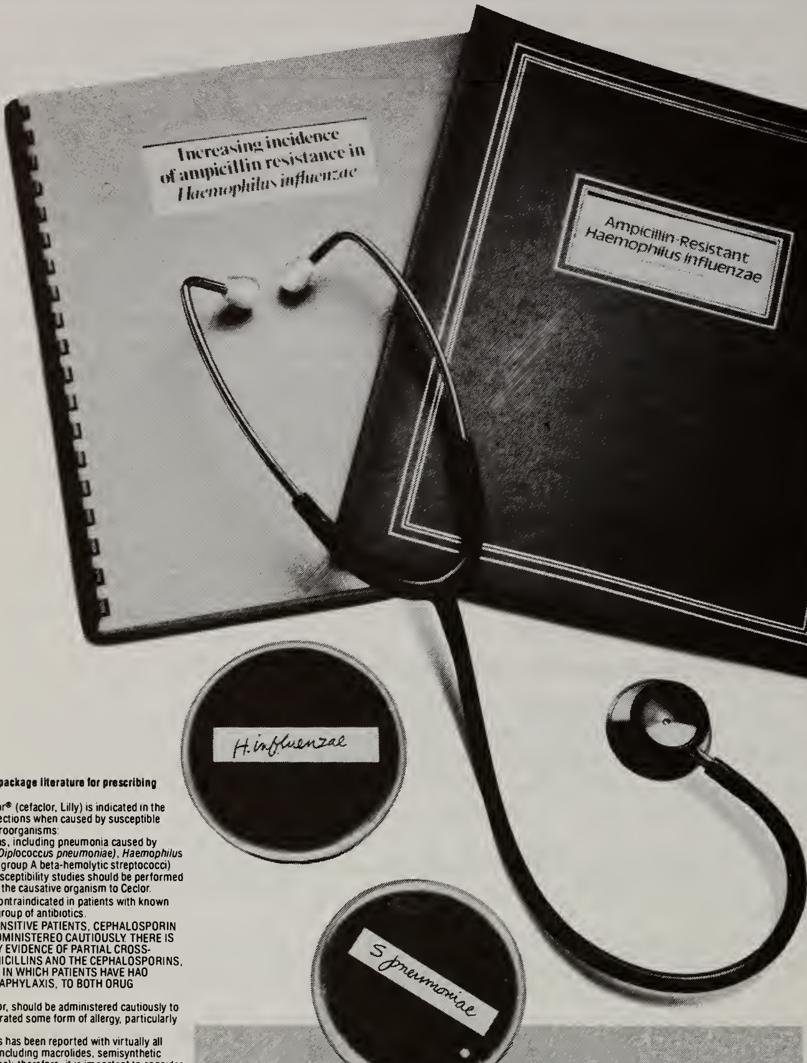
An added complication... in the treatment of bacterial bronchitis*


Increasing incidence of ampicillin resistance in Haemophilus influenzae
Ampicillin-Resistant Haemophilus influenzae
H. influenzae
S pneumoniae

Brief Summary. Consult the package literature for prescribing information.

Indications and Usage: Ceclor® (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae)*, *Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor.

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: *General Precautions*—If an allergic reaction to Ceclor occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy—Pregnancy Category B—Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers—Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor® (cefaclor, Lilly) is administered to a nursing woman.

Usage in Children—Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below:

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain—Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic—Slight elevations of SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic—Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal—Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

Some ampicillin-resistant strains of Haemophilus influenzae—a recognized complication of bacterial bronchitis*—are sensitive to treatment with Ceclor.[1-6]

In clinical trials, patients with bacterial bronchitis due to susceptible strains of Streptococcus pneumoniae, H. influenzae, S. pyogenes (group A beta-hemolytic streptococci), or multiple organisms achieved a satisfactory clinical response with Ceclor.[7]

Ceclor®
cefaclor

Pulvules®, 250 and 500 mg

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*Many authorities attribute acute infectious exacerbation of chronic bronchitis to either *S. pneumoniae* or *H. influenzae*.[8]

Note: Ceclor is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Additional information available to the profession on request from Eli Lilly and Company, Indianapolis, Indiana 46285.

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Drugs and Insomnia

NATIONAL INSTITUTES OF HEALTH

Introduction

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

The past decade has provided new developments and methodologies in sleep research, clinical practices, neuropharmacology, and psychiatric diagnoses. A taxonomy of sleep disorders has been advanced, and there are two newly marketed rapidly eliminated hypnotic drugs, as well as others under development. Use of a sleep-promoting medication is a decision that physicians and patients alike frequently encounter.

A recent national survey found that one-third of the population reported some degree of insomnia, and one-half of this group—17 percent of the population—considered the insomnia serious. Half of the group with "serious insomnia" reported a high level of emotional distress. Only 10 percent of the subjects reporting "severe" insomnia received prescribed sleep-promoting medications; 5 percent used over-the-counter compounds. Surveys of primary care practice indicate that the bulk of hypnotic drug therapy is directed to women and the elderly with medical or mental disorders, and only a very small proportion with a primary diagnosis of insomnia.

Since insomnia appears in different diagnostic contexts and occurs under a variety of circumstances, it is often difficult for the physician to know whether, when, and how to select and use hypnotics and other sleep-promoting medications. Yet, with the more extensive pharmacological and clinical information now available, more effective day-to-day clinical decision-making is possible.

As an aid to clinicians, the National Institute of Mental Health and the Office of Medical Applications of Research of the National Institutes of Health convened a Consensus Development Conference on November 15-17, 1983, to address these questions and develop principles to facilitate diagnosis and treatment. After a day and a half of presentation of data by experts, a Consensus Panel consisting of psychiatrists, psychopharmacologists, biomedical researchers, epidemiologists, primary care physicians, and public representatives considered the evidence and agreed on answers to the following questions:

1. Under what circumstances might a sleep-promoting medication be considered; in what types of sleep disturbances are sleep-promoting medications undesirable?
2. What are the pharmacologic factors to be considered in the selection of sleep-promoting medications?
3. What are the appropriate treatment strategies to be employed in using sleep-promoting medications on a short-term or long-term basis?
4. What are the principal cautions and risks associated with prescribing these drugs; what special considerations should be applied in regard to medical status, age, concurrent drug use, or other factors?
5. What research areas need further development?

Conclusions

Insomnia is a symptom or condition of heterogeneous origin. It signals the need for careful and systematic diagnostic inquiry. Primary medical, psychiatric, and other causes of insomnia should be identified and treated

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From the Office of Medical Application of Research, National Institutes of Health, Bethesda, Md.

Reprint requests to the Office of Medical Applications of Research, Room 216, National Institutes of Health, Bethesda, MD 20205 (Michael J. Bernstein).

accordingly. Treatment of insomnia should start with the assessment and necessary correction of sleep hygiene and habits. Psychotherapeutic, behavioral approaches and pharmacotherapy, alone or in combination, should be considered in the formulation of a comprehensive treatment plan. When pharmacotherapy is indicated, benzodiazepines are preferable. Patients should receive the smallest effective dose for the shortest clinically necessary period of time; this recommendation applies especially to the elderly. The choice of a specific drug should be based upon its pharmacological properties in conjunction with the particular clinical situation and needs of the patient. Physicians should educate and monitor patients in order to evaluate and reduce the risks of dependence, side effects, and possible withdrawal difficulties. The treatment of insomnia will advance further with better understanding of the pathophysiologies of sleep disorders, as well as with the improvement of sleep-promoting agents and techniques.

1. **Under what circumstances might a sleep-promoting medication be considered; in what types of sleep disturbances are sleep-promoting medications undesirable?**

Accurate differential diagnosis is essential to effective management of patients with insomnia. The first obligation of the practitioner is to search for a specific psychiatric or medical disease as the underlying cause. This view considers insomnia as primarily one symptom of a symptom complex, which can be assessed by an appropriate medical history, physical examination, and laboratory procedures. Evaluation of the sleep history should include a review of the patient's usual sleeping habits with specific description of the sleep complaint (e.g., difficulty falling asleep, sleep disruptions, intermittent or persistent), bedtime routines and review of waking schedule, and use of prescription and non-prescription medications and alcohol, and may be aided by the use of a sleep diary. Treatment should be directed toward the medical or psychiatric condition and, if treatment is successful, the insomnia ordinarily responds concommitantly. This, however, may not be the case with medical conditions involving considerable pain or debility, where insomnia may remain as an unresponsive symptom. Adjunctive treatment with sleep-promoting medication may be of use in such cases.

Another strategy typically employed by tertiary referral sleep disorder clinics emphasizes not only a sleep-medical history and extensive review of 24-hour functioning, but also, when appropriate, application of sleep laboratory procedures to evaluate day and night sleep and physiological patterns. While a specialized taxonomy emphasizes primary sleep disorders and sleep disturbances associated with psychiatric, medical, or drug-related conditions, others find the DSM III psychiatric classifications adequate. To date, neither general clinical practice (which can manage the majority of disorders) nor special sleep disorder procedures have produced unambiguous indications for sleep-promoting medication.

At this stage of evolving knowledge, it is convenient for purposes of discussion to divide the insomnias into transient insomnia, short-term insomnia, and long-term insomnia. While there is not complete agreement in the field, many experts state that individuals with *transient insomnia* are normal sleepers who experience an acute stress or situation for several days (e.g., air travel to a new time zone, hospitalization for elective surgery) which affects their sleep adversely. Some advocate the use of sleep-promoting medication, especially if the situation can be anticipated or it will last only several days. Others feel that reasons for the transient insomnia should be explored or the situation should be dealt with by tolerating the sleep loss or observing good sleep hygiene (e.g., caffeine reduction, regulation of hours in bed, and, for the traveler, the bedtime hour).

Short-term insomnia is usually associated with a situational stress (e.g., acute personal loss) often related to work and family life or serious medical illness. Since this type of insomnia may last up to 3 weeks, sleep hygiene and non-drug procedures, sleep-promoting medications may be considered.

Controversy exists over the indication for medication in *long-term insomnia.* The clinician should undertake an extensive differential diagnostic workup prior to a treatment decision. The available data suggest that insomnia in one-third to one-half of patients in this category is related to underlying psychiatric conditions. A second group consists of individuals whose insomnia is related to chronic drug/alcohol dependence or abuse. Other causes of long-term insomnia include medical conditions, sleep apnea, periodic leg movement (myoclonus), 24-hour rhythm disturbances such as advanced and delayed sleep phase, or psychophysiological insomnia (no apparent psychiatric or medical syndrome). Since the prevalence of sleep apnea and nocturnal myoclonus increases in the elderly, patients suspected of having these disorders need careful inquiry and investigation, often in sleep disorders clinics, before sleep-promoting agents are prescribed.

Non-drug strategies such as exercise, decreased caffeine intake, elimination of alcohol and drugs, trial of biofeedback/relaxation or other stress reduction techniques are indicated as the initial approach to psycho-physiological insomnia. A short trial (less than 1 month) of sleep-promoting medication concomitant with behavioral treatments may also be indicated.

Insomnia patients who have not responded to the aforementioned treatments and for whom major psychiatric or medical disorders have been specifically ruled out are the most appropriate for referral to a sleep disorders clinic. In addition to evaluation, such centers may provide specialized treatment. For example, the newer technique of chronotherapy for advanced and delayed sleep is warranted for selected individuals with work-shift schedule problems or other phase-shift sleep/wake problems, although qualified and interested practitioners can also learn and provide such treatment.

Several of the diagnostic categories of long-term insomnia may represent relative contraindications for sleep-promoting medications. While some practitioners have argued the case for sleep-promoting medication as an adjunct in psychiatric conditions, the appropriate treatment of the underlying condition usually will lead to improvement in sleep. One would only prescribe hypnotics to individuals with a known dependence on alcohol with considerable caution. The presence of sleep apnea, daytime sleepiness, or heavy snoring may also be reasons not to administer traditional sleep-promoting medications for long-term insomnia.

2. What are the pharmacologic factors to be considered in the selection of sleep-promoting medications?

Pharmacologic factors to be considered with hypnotic agents include the following: therapeutic index, dose, rate of absorption, lipophilicity, rate of tissue distribution, elimination half-life or clearance rate, presence or absence of active metabolites, presence or absence of drug interactions, and various pharmacodynamic characteristics which mediate drug effect.

The therapeutic index refers to the ratio of the lethal dose of a drug to its effective dose. The very favorable therapeutic index of the benzodiazepine class of hypnotic drugs more than any other factor accounts for the shift away from the barbiturates and related sleeping medications. Fatal overdoses are extremely rare unless these drugs are taken in combination with alcohol or other drugs. Since benzodiazepines largely have replaced other types of hypnotics, only pharmacologic characteristics of importance for this drug class will be discussed.

Dose is central to therapy because of the way it influences other pharmacologic factors. Although low lethality gives the physician considerable leeway in individualizing the dose for each patient, the principle of using the lowest effective dose is still a good guide in avoiding unwanted side effects.

Differences in rates of dissolution and absorption of benzodiazepine drugs from the gastrointestinal tract into the blood influence the time to peak plasma concentration and the time to onset of hypnotic effect. Significant differences in absorption rates have been reported for marketed benzodiazepine hypnotics, but sufficient clinical trial data are lacking to establish whether these are clinically meaningful. The rate of entry into the brain is governed largely by the solubility of drug in lipoid tissue, termed its lipophilicity. All benzodiazepines are relatively lipophilic. Where lipophilicity of two active agents is approximately equal, the rate of onset of hypnotic effect should be governed by dose and by rate of absorption from the GI tract into blood rather than by the rate of transfer from blood into the brain.

Along with dose, rate of tissue distribution and clearance rate of a drug determine its duration of action. A convenient way of estimating clearance is in terms of a drug's elimination half-life. The more slowly eliminated hypnotic is more apt to produce unwanted daytime sedation and to accumulate in the body with chronic administration. In recent years, drug development has focused on more rapidly eliminated (shorter half-life) benzodiazepine hypnotics in order to minimize these potential disadvantages. Two shorter half-life benzodiazepines are now approved as hypnotics: temazepam, with a half-life of 8-12 hours, and triazolam, with a half-life of 3-4 hours. Actually, several shorteracting benzodiazepines have been available for a number of years (e.g., oxazepam), but they have been promoted as anxiolytics. When given at appropriate dosage, these are effective hypnotics and are not associated with significant daytime sedation or cumulative effects. However, the short half-life may be associated with occasional next-day memory difficulties and with chronic use unwanted tolerance and decreased hypnotic effect may occur, as discussed in question #4.

Many benzodiazepines have several active metabolites. For example, flurazepam has two rapidly eliminated metabolic products, hydroxyethyl flurazepam and flurazepam aldehyde, and the slowly eliminated metabolite desalkylflurazepam with a half-life ranging from 40-100 hours. These various metabolites of flurazepam largely determine its clinical actions, both acute and chronic, but add complexity to its use with chronic administration and in the older patient. Triazolam and temazepam (like oxazepam and lorazepam) are not thought to have any significant active metabolites.

Although the benzodiazepines in therapeutic doses generally do not appear to inhibit or enhance the metabolism of other drugs, their effects do interact with those of ethanol and other sedative hypnotics. Thus CNS depressant effects of alcohol and the other benzodiazepines are addictive. Furthermore, ethanol can slow the normal rate of liver metabolism of the benzodiazepine thereby increasing levels of the hypnotic drug. As another example, cimetidine significantly impairs the metabolism of most benzodiazepines, except for those metabolized exclusively by conjugation.

Finally, there are several pharmacodynamic factors that need to be considered. The problems of tolerance and neuronal adaptations, which are responsible for withdrawal symptoms and rebound insomnia, are discussed in question #4.

The interplay of these pharmacologic factors is important in achieving various clinical objectives, and often there is a balancing or tradeoff of one against the other. For example, it is possible to obtain a faster rate of onset by raising the dose, but this in turn may prolong duration of effect leading to unwanted daytime sedation, hangover, or memory problems. One drug may be preferred for a sleep latency problem and another for a problem of sleep maintenance or insomnia associated with high levels of anxiety. These differences in pharmacologic characteristics of the benzodiazepine hypnotics can be utilized in special clinical circumstances in order to individualize treatment.

3. What are the appropriate treatment strategies to be employed in using sleep-promoting medications on a short-term or long-term basis?

Patients should be considered for sleep-promoting drug therapy when they are significantly troubled by the presence or possibility of inadequate sleep or when the physician is concerned about the deleterious impact of disturbed or inadequate sleep on the patient's health, safety, and well-being.

As stated in question #1, the strategy should begin with an appropriate medical history and physical examination, with the identification, whenever possible, of potentially treatable causes of insomnia. The strategies for transient insomnia, short-term insomnia, and long-term insomnia will differ.

Transient insomnia refers to insomnia related to minor situational stress (e.g., hospitalization for elective surgery, jet travel). For this type of insomnia, drug treatment may or may not be necessary. Where elected, the treatment should be a small dose of a rapidly eliminated hypnotic unless sustained sedation is desired. Treatment may be needed for 1 to 3 nights.

Short-term insomnia is usually related to stress associated with work and family life, such as job loss, bereavement, or illness. For this type of insomnia, it is particularly important to educate the patient in regard to desirable sleep routines, including the avoidance of caffeine, alcohol, daytime naps, going to bed too early, etc. Simultaneously and during maintenance of good sleep hygiene, a benzodiazepine hypnotic may be used. If drug treatment is elected, the smallest effective dose should be used, with titration of dose if necessary, and for a treatment period usually of not more than 3 weeks.

Intermittent use of the drug is advisable, with skipping of nightly dosage after 1 or 2 good night's sleep. A benzodiazepine with a short half-life may be preferable if significant anxiety is not present, or to avoid unwanted daytime sedation. For other patients, a benzodiazepine with a long half-life may be preferable. Discontinuance of therapy should be carried out gradually.

Before a drug is chosen, the patient should be questioned about previous experience with specific medications. Therapy should also be individualized to take into account such factors as age and weight.

Patient/physician contact should be maintained, at least by phone, to achieve optimal dosage and monitor side effects. Patient education may include the use of written materials to reinforce verbal instruction on the benefits and hazards of drug therapy.

Long-term insomnia requires special medical, physiological, and psychiatric evaluation, as described under question #1. If a major psychiatric disorder exists, it needs to be treated appropriately. Specific treatment for chronic medical disorders may still leave a need for treatment of associated insomnia. In addition, certain specific sleep disturbances, such as sleep apnea, may need to be ruled out before treatment is undertaken for insomnia.

Long-term insomnia not attributable to disorders such as the above is best treated with a combined approach, employing sleep-promoting agents along with psychological-behavior therapies, such as relaxation techniques, sleep curtailment, or stimulus control therapy to undo negative conditioning related to sleep habits.

Benzodiazepines are the drugs of choice, and intermittent usage, such as 1 night in 3, is advised. This intermittent usage allows assessment of the possibility of discontinuing therapy. A benzodiazepine with a long half-life would seem appropriate in this circumstance. If benzodiazepines do not meet the patient's needs, the physician may elect to prescribe a sedative anti-depressant, e.g., amitriptyline 25-100 mg at bedtime.

For patients who respond to this program, it is wise to discontinue therapy gradually after 3 to 4 months. Patients who do not respond to treatment may have to be reevaluated for the possibility of other medical or psychiatric disorders or be referred to a sleep disorders clinic (see question #1).

4. What are the principal cautions and risks associated with prescribing these drugs; what special considerations should be applied in regard to medical status, age, concurrent drug use, or other factors?

The risks associated with pharmacologic treatment of sleep disturbance vary with the patient, the situation, the condition (type of sleep disturbance) being treated, and the specific agent selected. Since the benzodiazepines are now the sleep-promoting agents of choice, our discussion focuses on them.

Perhaps the most common risk associated with the use of the benzodiazepines is diminished daytime performance as a result of carryover effects. Despite the development of some degree of tolerance, cognitive or psychomotor impairment can be a significant problem for many patients when more slowly eliminated benzodiazepines are given over a period of weeks. Even with short term use of slowly eliminated drugs, decreased performance the next day is a potentially serious risk for individuals in those occupations requiring high levels of visual-motor coordination. This problem can be reduced by using lower doses or more rapidly eliminated drugs.

All sedative-hypnotics, including the benzodiazepines, cause systematic alterations in the architecture of sleep (e.g., decreased amount of delta wave sleep) and raise thresholds for arousal from sleep. The practical implications of these observations are presently unknown.

Benzodiazepines can interact with a number of other drugs commonly used by patients with insomnia (see question #2), but the practical significance of these interactions is uncertain. An important interaction is that with alcohol, where the psychomotor impairing effects are additive. This interaction is of concern since the subjective sense of intoxication may not be enhanced. Further, with the slowly eliminated benzodiazepines, plasma levels may persist for days after benzodiazepine use has ceased.

Drug dependence on sedative-hypnotics (i.e., psychological dependence and compulsive drug use) has been recognized for more than 100 years. The shorter-acting barbiturate and the shorter-acting non-barbiturate hypnotics (e.g., methaqualone, glutethimide) represent a greater risk in this respect than the more slowly eliminated benzodiazepines. There is as yet too little experience with the more rapidly eliminated benzodiazepines to gauge their dependence liability relative to other benzodiazepines when prescribed for sleep disturbance. The development of dependence can be minimized by limiting the amount prescribed and the duration of use and by careful monitoring of use and refills.

Adaptive changes to the actions of general CNS depressants and benzodiazepines probably begin with the first doses given. These changes are responsible for the partial tolerance that typically develops with the sleep-promoting and psychomotor-impairing effects of these drugs, as well as for rebound and withdrawal phenomena. Even after short periods of use, if the benzodiazepines could be abruptly removed from their sites of action, in most cases some rebound or withdrawal phenomena would be detectable with appropriate measuring instruments. Technically, this represents physical dependence. However, unless high doses of benzodiazepines are used for several weeks or lower doses are used for a number of months, physical dependence is not likely to be of sufficient severity to cause major clinical problems. With the more rapidly eliminated benzodiazepines, and to a far lesser degree, with the more slowly eliminated benzodiazepines, some rebound exacerbation of sleep disturbance may occur when the drugs are discontinued. Tapering the dose can reduce, but probably not eliminate, this problem entirely. The more rapid onset of these rebound effects after discontinuing the more rapidly eliminated drugs could, in theory, increase the tendency of the patient to believe they are needed for continued satisfactory sleep. Good management should include preparing the patient for this transient exacerbation of sleep disturbance when the drugs are reduced or stopped.

Clinically significant withdrawal phenomena of varying intensity can occur when benzodiazepines have been administered for prolonged periods especially if the daily dosage has exceeded the recommended amounts. Based on experience with barbiturates, the severity of withdrawal may prove to be considerably greater if more rapidly eliminated benzodiazepines are abused for prolonged periods and are then abruptly discontinued.

In the past, suicide was frequently accomplished by the ingestion of barbiturate and non-barbiturate hypnotics. Although the benzodiazepines carry less risk of fatality in such situations, caution is nevertheless indicated where suicide is a potential concern. Caution must be taken to write prescriptions for a limited period of time and to monitor refills so that the drugs cannot be readily utilized in a lethal fashion. When benzodiazepines are lethal, it is usually because they are combined with alcohol or other drugs.

Certain populations require special considerations. Aged patients, who tend to clear drugs more slowly and who are more sensitive to a given blood level of benzodiazepines, are more likely to develop cognitive and motor impairments when given the more slowly eliminated benzodiazepines. Ataxia and problems with memory and thinking are possible complications that may not appear until several weeks after beginning treatment. Similar problems may develop in younger patients on renal dialysis or with impaired hepatic function. Dosages for these populations must be carefully adjusted, and more rapidly eliminated drugs are preferable. The physician must be alert to the possibility of drug interactions for all patients, but most especially for this elderly group which is often being treated with other drugs.

Sleep apnea is more common among obese or elderly patients, especially males. Treatment with any hypnotic may exacerbate sleep apnea. While reports of death due to using hypnotics in therapeutic doses are rare, laboratory studies show an increase in frequency and duration of apnea episodes and a decreased dioxide saturation of blood.

Pregnant patients also require special attention since all benzodiazepines carry special warnings for this population.

Patients with histories of alcoholism or other types of drug dependence are at higher risk for developing dependence on sedative hypnotics and benzodiazepines.

5. What research areas need further development?

A number of areas deserve research attention and support by health research agencies. These include epidemiologic studies on insomnia in the general population as well as in the primary care office setting, including specific complaints that bring insomniacs to doctors. Such studies should describe patients' demographic and medical characteristics and consider factors related to physicians' prescribing patterns for sleep-promoting drugs. Also needed are studies of the cost effectiveness of various diagnostic and treatment approaches. The role of sleep disorders centers in providing diagnostic and therapeutic guidance, criteria for referral and, in particular, their potential for generating sound clinical research, should be studied. Also deserving of study is the process of self-treatment by insomniacs, including the magnitude, therapeutic performance, and adverse effect record of over-the-counter hypnotic drug usage. The nature and extent of daytime performance deficits in insomniacs, with and without treatment, is not adequately documented. We need to know the somatic, psychological, social, and economic costs of untreated insomnia, and the impact (positive or negative) on these costs of various therapeutic approaches, especially in long-term insomnia. Research should continue on the function and physiology of normal sleep and the pathophysiology of abnormal sleep. Finally, the search for new and better treatments for insomnia should continue.

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The Origins of Anesthesia: Part II

SHERWIN B. NULAND, M.D.

VITALISM, MESMERISM, and HYPNOSIS

In some ways, a chapter devoted to non-pharmacologic methods of anesthesia is a digression from the main course of this volume's purpose. However, the concept of mesmerism intertwined both its mystical and functional aspects into the beginnings of the ether era in a linkage so intimate that it plays a part in the story which is not only colorful, but worthy of recording as an example of the medical thinking of the time.

Until recent years the medical world has looked with a skeptical and often scornful eye upon techniques that are not subject to scientific analysis. Especially when such techniques have been introduced in an extrascientific way or by promulgators who have flirted with the far peripheries of rational thought, medical science has tended to refuse its approval. In this regard, medical science has almost always been right. For it is an indubitable truth that, regardless of the few exceptions, when the scientific community has evaluated an idea and called it crackpot, it has almost always proved to *be* crackpot.

But it is also well-known that from crackpot concepts may arise useful theories and useful tools. If a fanciful idea has a credible seed or a credible offshoot, they will often implant themselves and eventually flourish, once the climate has become less poisoned by their original associations. So it may prove to be with hypnosis.

Goethe once pointed out that mysteries are not necessarily miracles, and perhaps it was this line of thinking that had led Franz Anton Mesmer of Vienna (1734-1815), just a bit earlier, to introduce the doctrine of vitalism. As a philosophical theory it consists simply of the belief that there is something in living organisms that cannot be explained by the principles of physical or natural science, and it is precisely that "something" which distinguishes living from non-living structures. The vitalists believed that the activities which characterize living organisms are made possible by this force (life, if you will) which is not possessed by inanimate objects. The concept of a vital essence runs a continuing, if often wandering, course through medical history and has, at various times, been thought of as fluid, such as the blood, or spirit, or, as by Mesmer, a kind of cosmic energy or animal magnetism.

Believing that the animal magnetism could be used to treat disease by transmitting the force from his own body to that of a patient, Mesmer had some striking successes. Presumably, these tended to occur in patients having symptoms which we would now recognize as being psychogenic. Although Mesmer sincerely believed that he was making use of a true magnetic healing power which flowed from his body, clearly what he was using was hypnosis and suggestion.

Mesmer was unfortunately undone by his own success, because patients began to come to him in such huge numbers that he had to develop wholesale techniques to treat them, such as pointing energy-invested sticks at groups of sufferers. He was driven out of Vienna by a medical establishment which accused him of practicing magic, but soon became very influential in Paris, where his popularity, if not his credibility, was enhanced by certain aspects of his hypnotic seances which were pure theater. The sight of the master of animal magnetism dressed resplendently in a beautifully tailored lilac suit, playing tunes on his harmonica, touching his enthralled patients with his magical wand or leading them to join hands around a so-called "magnetic tub" raised the hackles of French scientists and physicians, who were able to prevent him from being licensed to practice medicine in their country. Eventually, they convinced the Crown to have him investigated, and a commission was appointed in 1784, three of whose members were Benjamin Franklin, Antoine Lavoisier, and the soon-to-be notorious Dr. Joseph Ignac Guillotin. Shortly after

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the commission declared the prophet a fraud, he dropped out of sight, and very little was heard from him until he died in 1815.

Franz Anton Mesmer left a profound mark on the history of medicine, and certainly on the history of anesthesia. Although until recently tangential to the mainstream of progress, concepts such as hypnosis and suggestion are once again the subject of inquiry, although now, as before, much of the investigation and utilization are in the hands of individuals who are beyond the boundaries of scientific thought. Fortunately, however, serious researchers are turning their attention to these phenomena, and the promise of useful discoveries is an increasingly alluring one. In fact, from its very beginnings, there have always been medical and non-medical thinkers who have, in a systematic way, tried to squeeze some sense out of the claims made by adherents of hypnotic methods. In tracing the history of anesthesia in the 19th century, two such workers can be identified, who became involved in testing the use of mesmerism as a means of surgical anesthesia, John Elliotson (1791-1868), and James Esdaile (1808-1859).

Of these two, the first and more prominent was Elliotson. As the first Professor of the Practice of Medicine at the new University of London and Senior Physician to the University College Hospital, his was considered one of England's outstanding medical minds. Deeply interested in experimental medicine and particularly in the physiology of the nervous system, Elliotson became a student of phrenology and of mesmerism. Mesmerism was at that point attracting the moderate interest of a few other European physicians, and it had even been reported that Dr. Jules Cloquet had, on April 12, 1829, removed a breast while the patient was under hypnosis. Due note was taken of that operation in an address given by Dr. George Sigmond on assuming the Chair of Materia Medica of the Medico-Botanical Society of London in 1834. Sigmond's address provides a clear exposition of the way in which Mesmer was viewed by the British scientific community. It should not escape notice that the word *anesthesia* is used in the text so matter-of-factly that it seems unlikely that Sigmond's audience was not familiar with it.

Elliotson began to carry out clinical experiments with patients, which soon attracted many observers, medical and non-medical alike, and quickly became a thorny issue in hospital politics, and, indeed, in the medical politics of London itself. Thomas Wakly, the irascible editor of the *Lancet,* attacked Elliotson and what the journalist liked to call the "Mesmeric Humbug" in the pages of his periodical. All of the controversy engendered by Elliotson's experiments culminated in the passage of a resolution by the Council of University College on December 27, 1838, forbidding any further work with mesmerism or animal magnetism. Elliotson, his Scottish temper ablaze, resigned his affiliations with both the College and its hospital.

The termination of John Elliotson's academic affiliations not only did not end his work with animal magnetism, but had quite the opposite effect. He now began to pursue his experiments with a kind of missionary zeal, and his strictly scientific methods began to become interlarded with a slightly lunatic quality. He founded a quarterly called *The Zoist: a Journal of Cerebral Physiology and Mesmerism, and their Applications to Human Welfare,* the pages of which contained writings that ran the gamut from scholarly articles by outstanding contemporary thinkers to a description of the mesmeric cure of a cow and instructions on how to choose a mesmerizer. Such a choice was obviously likely to be a bit hazardous in its implications, as witnessed by the case reported in *The Zoist* of a couple whose advisor convinced them to christen their baby Mesmer.

Nevertheless, in the midst of all this flap and twaddle, Elliotson continued to make serious observations, among which were descriptions of surgical operations performed under hypnosis. In 1843, he published a long phamphlet, entitled *Numerous Cases of Surgical Operations without Pain in the Mesmeric State.* It is on page 65 that Elliotson uses the word *anesthesia:* "For a length of time she had perfect loss of the sense of touch,—anesthesia, in her ecstatic delirium."

Elliotson's professional reputation, although a bit tattered by the mesmeric controversies, remained essentially intact. In 1846 he was chosen to deliver the Harveian Oration of the Royal College of Physicians. Rarely before or since have the Fellows of the College heard a more eloquent or scholarly dissertation. In impeccable Latin, Elliotson described the viciousness of the opposition that had been endured even by such benefactors of mankind as Harvey and Jenner, so much like the ridiculing abuse to which he and his supporters were now being subjected. He implored the Fellows to give objective evaluation to the principles of mesmerism, but he was determined that his words should reach an even wider audience as well. With this in mind, he published the Oration in both its original Latin and in English.

It was in Elliotson's *Zoist* that the English-speaking world first heard of a series of surgical operations carried out in East India which remains to this day the outstanding example of hypnotism's potential as a method of anesthesia. The operations were reported by Dr. James Esdaile, Director of the Native Hospital at Hooghly, near Calcutta. Having read of Elliotson's work, Esdaile succeeded in a major operation under hypnosis on April 4, 1845, although it did take his patient 13 hours to come out of the trance. Following a series of successes, his work received a favorable report from a commission appointed by the Governor of Bengal, as a result of which a small facility, thereafter known as the Mesmeric Hospital, was given over to him to continue his investigations. This quotation from the

Commissioner's report describes the technique used at Hooghly:

> *The patients treated were all native males, from 18 to 40 years old, Hindoos and Mahomedans, in all conditions of general health from extreme emaciation to ordinary strength .... The mesmerisers employed by Dr. Esdaile were young men. Hindoos and Mahomedans, from 14 to 30 years of age, most of them compounders and dressers from the Hooghly Hospital.*
>
> *To each patient a separate mesmeriser was assigned. The room in which they operated was darkened, but from time to time the Committee were enabled to witness, through small apertures made in the door panels, the manner in which the processes were carried on. The patient lay on his back, the body naked from the waist upwards, and the thighs and legs bare; the mesmeriser seated behind him at the head of the bed, leaning over him, the faces of both nearly in contact, the right hand being generally placed on the pit of the stomach and passes made with one or both hands along the face, chiefly over the eyes. The mesmeriser breathed frequently and gently over the patient's lips, eyes and nostrils. Profound silence was observed. These processes were continued for about two hours each day in ten cases, for eight hours in one case in one day, and for six hours in another case, without interruption. Three cases of the ten ... were dismissed without satisfactory effect.*

Esdaile continued to practice mesmerism in India until 1851, when his 20 years service came to a close. Returning to his native Scotland, he was frustrated by his inability to achieve any measure of success with it when used on the local population at home.

Unlike some of his fellow mesmerists, Esdaile approached the use of his technique with a good degree of objectivity. As successful as the method was in his own experience, he welcomed the advent of ether, having been quite impressed with his own trial of that agent in 1847. Although committed philosophically to mesmerism as a useful means of treating medical diseases, he recognized that it was less efficient in producing surgical anesthesia than ether or chloroform, and certainly far less predictable. Most observers who had witnessed what Esdaile referred to as "the drudgery required to induce mesmeric insensibility to pain" agreed with him. Pragmatic rather than philosophic considerations were the real reason for the rapid decline in mesmeric anesthesia methods after the remarkable events of October 16, 1846.

The field of mesmerism should not be left without a reference to the work of James Braid (1795-1860), a surgeon who practiced in the city of Manchester. After several years of studying mesmeric phenomena, Braid came to the conclusion that the theory of animal magnetism was untenable, and that the mesmeric trance could be best explained as being a personal or subjective state which can be self-induced by the patient under the influence of staring at a bright inanimate object. He proved to his own satisfaction that no fluid or no force passes from operator to patient, and that there is no magical component to the method. Rejecting the mesmeric theory but recognizing that the phenomenon of the trance is real, he attributed it to the power of suggestion—he called it hypnosis. Under this name and with its true nature revealed, the mesmeric state has been and will continue to be a valuable technique in psychological research and in the alleviation of human misery.

PNEUMATIC MEDICINE, LAUGHING GAS, and ETHER FROLICS

Although surgical anesthesia was not born until the middle of the 19th century, it was undergoing an active gestation for more than 100 years before that, a gestation to which major contributions were made by a host of brilliant experimenters. The list of those contributors includes names which, although renowned for researches in other areas of science, are not usually thought of in relation to clinical medicine, such as John Dalton, Joseph Priestley, Antoine Lavoisier, James Watt, Humphrey Davy and Michael Faraday. The involvement of these men came about because of the parallel and sometimes interlacing development of two areas of study, namely the chemistry and physics of gases on the one hand and the physiology of respiration on the other.

Nitrous Oxide Before Horace Wells

The one man most responsible for introducing modern chemical and physical studies of gases was Joseph Priestley (1733-1804), a politically controversial Nonconformist minister whose contributions were made particularly noteworthy by the fact that he had never had even the rudiments of what passed, in 18th century England, for a scientific education. Although his autodidactism resulted in some problems dealing with theoretical concepts (as manifested in his inability to discard the phlogiston theory), it did not prevent him from describing nitrous oxide in 1772, isolating oxygen in 1774, and giving the world the incomparable gift of man-made soda water. Both the soda water and the nitrous oxide discoveries were described in his *Observations on Different Kinds of Air,* published in the *Philosophical Transactions of the Royal Society.*

As Priestley's work with gases became known, and as Lavoisier made his signal contribution in elucidating the nature of oxygen and its function in respiration, scientists began to look for ways in which the new knowledge could be used to treat disease, most particularly pulmonary tuberculosis. The leading architect of this movement was Thomas Beddoes (1760-1808), whose interest in therapeutic inhalation resulted in the founding of the "Pneumatic Medical Institution," in Bristol, England, in 1798, and the appointment of the 20 year old Humphrey Davy (1778-1829) as its first Superintendent of Experiments. It has been said that Davy, released by his new employer from his indentured service to a surgeon-apothecary of Penzance, was Beddoes' greatest discovery. Within a year of assuming his duties at the Institute, Davy described the intoxicating effects of inhaling nitrous oxide, a study he had begun with self-experiments in 1795. Another great scientific figure had appeared on the pneumatic scene shortly before this, in the person of James Watt (1736-1819), who prepared much of the apparatus for the Institute, no doubt to a large extent motivated by his own son's impending death of consumption.

Not content with studying the effects of nitrous oxide on himself and upon animals, Davy began to use in his researches as extraordinary a group of experimental subjects as has ever been assembled in the name of science, namely the leaders of the intellectual circle of Bristol, including Samuel Taylor Coleridge, Robert Southey and Peter Roget. With such articulate experimentees to interview, as well as his own considerable powers of observation, Davy produced a book which has become a classic in the history of science, *Researches, Chemical and Philosophical: Chiefly Concerning Nitrous Oxide, or Dephlogisticated Nitrous Air, and its Respiration.* The author was 22 years of age, and the publication of this volume in 1800 marks his first major contribution in what was to be a magnificently productive career. Davy was gifted with the ability to write clear and graphic descriptions, and was a popular lecturer and talented amateur poet; Coleridge said of him that if "he had not been the first chemist, he would have been the first poet of his age." Although that may have been the generous statement of a good friend, the following sentences shed light not only upon his powers of observation, but on his gift of literary exposition as well. The passages are to be found between pages 458 and 465 of *Researches*, and they describe the state of analgesia which Davy experienced as a consequence of breathing nitrous oxide:

> *In one instance, when I had head-ache from indigestion, it was immediately removed by the effects of a large dose of gas; though it afterwards returned, but with much less violence. In a second instance, a slighter degree of head-ache was wholly removed by two doses of gas.*
>
> *The power of the immediate operation of the gas in removing intense physical pain, I had a very good opportunity of ascertaining.*
>
> *In cutting one of the unlucky teeth called dentes sapientiae, I experienced an extensive inflammation of the gum, accompanied with great pain which equally destroyed the power of repose, and of consistent action.*
>
> *On the day when the inflammation was most troublesome, I breathed three large doses of nitrous oxide. The pain always diminished after the first four or five inspirations; the thrilling came on as usual, and uneasiness was for a few minutes, swallowed up in pleasure. As the former state of mind however returned, the state of organ returned with it; and I once imagined that the pain was more severe after the experiment than before.*

The possibility of using such an analgesic effect was not lost to the former surgeon's mate. In the section devoted to *Conclusions,* Davy permits himself the following speculation:

> *As nitrous oxide in its extensive operation appears capable of destroying physical pain, it may probably be used with advantage during surgical operations in which no great effusion of blood takes place.*

The caveat expressed in the final portion of the statement is explained by Davy's belief, unconfirmed by his own observation, that nitrous oxide increases the force of the circulation.[1]

Although Davy's was certainly the first reference to the possibility of using nitrous oxide as an inhalation anesthetic, neither he nor the contemporary scientific community recognized the potential implications of his conjecture. Davy, in fact, soon turned his attention away from nitrous oxide and therapeutic inhalation, resigning his position at the Pneumatic Institution in 1801, to become Director of the Chemical Laboratory of the recently established Royal Institution in London. His contributions from that point on were entirely in the realm of non-medical chemistry and physics.

The results of Davy's nitrous oxide experiments did have, however, a profound, even if indirect, effect upon the history of anesthesia. For it was from the Pneumatic Institution that the word went out that the gas was indeed "a gas," to invoke the lingua franca of the 1980's. Southey referred to the effects it had upon him as "a sensation perfectly new and delightful." The imaginative Coleridge, not yet ravaged by opium, found that inhaling nitrous oxide provided him "a highly pleasurable sensation of warmth over my whole frame" and the inclination to "laughing at those who were looking at me." Other visitors to the Institution were encouraged by Beddoes and Davy to try the gas so that their experiences might be recorded, and before long nitrous oxide, or laughing gas as it was soon to called, became well known as an apparently harmless and often hilarious form of entertainment.

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[1] It is an indication of Davy's prescience that, within a short time after anesthesia came into general use, his prediction was confirmed empirically. The situation is well described by a comment made in a recent editorial in the *Journal of the Royal Society of Medicine* (75, 149, 1982), describing early experiences after the introduction of ether anesthesia: "It was soon observed that patients operated upon under general anesthesia appeared to lose rather more blood than formerly, but at that time this must have seemed a disadvantage of comparatively little importance."

Sulfuric Ether Before Morton

Because it is customary to think of laboratory chemistry as a development of the past two centuries, the statement that ether was first synthesized in 1540 may come as a surprise. It is to a 25 year old Prussian botanist, Valerius Cordus (1515-1544) that the credit goes at that early date for distilling what was known as "sour oil of vitriol" (sulfuric acid) with "strong biting wine" (ethyl alcohol) to produce the "sweet vitriol," which under the name of sulfuric ether (actually diethyl ether), was to change the course of medical history 300 years later and 7,000 miles away. Although Cordus had no way of knowing it, he was observing a two-stage reaction from which water and ether distilled off:

1. $C_2H_5OH + H_2SO_4 \rightarrow H_2O + C_2H_5\ HSO_4$
2. $C_2H_5\ HSO_4 + C_2H_5OH \rightarrow H_2SO_4 + (C_2H_5)_2O$

Over the course of the next three centuries, a number of workers synthesized sweet vitriol, including Robert Boyle in 1680 and even Sir Isaac Newton, in 1717. Johannes Augustus Siegmundus Frobenius, a German chemist who seems to have worked in Boyle's laboratory, gave the name sulfuric ether to the extremely volatile liquid. Finally, in 1819, John Dalton published a definitive paper dealing with the compound's physical and chemical properties, *Memoir on Sulfuric Ether.*

Meanwhile, observers were beginning to note the lethargy and sleepiness that ether was capable of producing, and as early as 1818 a note appeared in the *Quarterly Journal of Science and the Arts* describing the result that might be expected from inhaling its vapor, pointing out that "it produces effects very similar to those occasioned by nitrous oxide." This article, although published anonymously, is generally attributed to Michael Faraday, then 27 years of age. The effect of inhaling ether was also well known, as noted earlier, to Thomas Beddoes and to Humphrey Davy, who themselves had had personal experiences with it.

Serious investigators were not the only ones to take note of the effects of ether vapor. Social gatherings called ether frolics became a well-known entertainment, often among students. Ether frolics and laughing gas parties were popular forms of social escapism quite familiar to the subsequent workers in surgical anesthesia, with obvious outcome.

(to be continued)

AMA BOARD OF TRUSTEES voted to recommend to the House of Delegates that there be no increase in dues for 1985 because of the members' commitment to the voluntary one-year freeze on physician fees. Regular member dues would be maintained at the rate of $330 for next year. Meeting in Chicago, the board also approved a strategic plan on future directions and resource needs. The three-year plan calls for an increase in revenues that can be accomplished either by increasing membership in the Association or eventually raising dues by a total of $60 over the two-year period from 1986-87. In a separate action, the trustees agreed to continue efforts to increase the proportion of non-dues revenue.

DUES-EXEMPT MEMBERS represent a disproportionately large segment of the total AMA membership, the Board of Trustees said in a recommendation to revise current policy. The board will ask the House of Delegates to limit dues-exempt status to physicians with financial hardship or disability, and physicians who are both 70 years of age or older and fully retired. Most physicians who were exempt under the previous criteria will continue to be exempt under a grandfather clause. If the house adopts the recommendation, dues for physicians who are both 70 years of age or older and who are working no more than 20 hours per week would be one half of regular dues. The board noted that 40,000 members are currently dues-exempt. They represent about 15% of the total membership.

—AMA *Newsletter,* May 2, 1984

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Logan v. Greenwich Hospital Association

SUPREME COURT OF THE STATE OF CONNECTICUT

Martha Logan v. Greenwich Hospital Association Et Al.(10969)
HEALEY, PARSKEY, SHEA, GRILLO AND BIELUCH, JS.

The plaintiff, claiming medical malpractice, sought damages from the defendant hospital and the three defendant physicians, N, an internist, B, a urologist, and D, a radiologist, for allegedly negligently caused injuries she sustained as a result of a kidney biopsy performed on her by B at the hospital. The trial court directed verdicts in favor of both the hospital and D, and the jury returned a verdict in favor of N and B. On the plaintiff's appeal to this court, *held:*

1. The trial court erred in instructing the jury that a physician, in obtaining a patient's informed consent, need not discuss with him any alternative which is more hazardous than the treatment the physician has recommended; accordingly, the matter was remanded for a new trial limited to the issue of whether B, whose duty it was to do so, had, in fact, obtained the plaintiff's informed consent to the procedure in question.
2. Although the trial court should, as requested by the plaintiff, have amplified its charge to the jury on the evaluation of expert testimony, its failure to do so was not substantially harmful to her.
3. The trial court's reference in its charge to the evidence was not so deficient that, as claimed by the plaintiff, it failed to serve as an adequate guide to the jury.
4. The plaintiff could not prevail on her claim that the trial court erred in charging that a physician is not liable for a bona fide error in judgment, she having failed to raise in the trial court the ground on which she based that claim on appeal.
5. The plaintiff was not harmed by the trial court's limitation of the applicable standard of care to that followed by physicians practicing in Connecticut, no evidence having been introduced that elsewhere different standards were followed in any of the specialties here in question.
6. The trial court did not err in directing verdicts in favor of both the hospital and D.
7. Since N did not participate in the biopsy operation, the plaintiff's claims of negligence in the performance of that procedure were inapplicable to him; more, as the referring physician, he had no obligation to inform the plaintiff of viable alternative procedures, but could reasonably have relied on B, a specialist, to provide that information which the plaintiff claimed she had not received.
8. There was no error in the trial court's denial of the plaintiff's request for an individual poll of the jury.

Argued June 3—decision released September 6, 1983

Action to recover damages for alleged medical malpractice, brought to the Superior Court in the judicial district of Fairfield at Bridgeport and tried to the jury before *McGrath, J.;* the court granted the motions of the named defendant and of the defendant Forbes Delany for a directed verdict, and the jury thereafter returned a verdict for the remaining defendants; from the judgment rendered thereon, the plaintiff appealed to this court. *Error in part; new trial.*

Shea, J. In this medical malpractice action the trial court directed a verdict for the defendant hospital and for one of the three doctors whom the plaintiff had named as defendants. The jury returned a verdict for the other two defendant doctors. The plaintiff has appealed, claiming error in the direction of the verdicts and in the charge to the jury. **The principal issue raised involves the propriety of the court's instruction that the duty of a physician to advise a patient of possible alternatives in obtaining an informed consent to a contemplated operative procedure does not require the disclosure of a more hazardous alternative. We find error in this instruction and order a new trial limited to the absence of informed consent theory of the complaint.** *[Emphasis added, Ed.]* We affirm, however, the direction of a verdict for two of the defendants as well as the verdict reached by the jury for one of the defendants whose request for a directed verdict was denied.

The evidence was that the defendant Dr. N., a specialist in internal medicine, first met the plaintiff in July, 1971,

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Case, 191 Conn. 282, Vol. 191, *Connecticut Law Journal*, September 6, 1983.

following the birth of her twin children at the Greenwich Hospital. After her discharge from the hospital on August 4, 1971, the plaintiff continued to consult him because of continued pain, swelling and a decreased range of motion. She was hospitalized for ten days in February, 1972, because of pain in her neck, shoulders, arms, and legs which interfered with her sleeping.

In August, 1972, Dr. N. advised the plaintiff that she had systemic lupus erythematosis (lupus). In October, 1972, he advised her to undergo a kidney biopsy to determine the extent of lupus involvement in her kidneys. He explained that the biopsy was a simple procedure, which would be carried out under a local anesthetic, that she might suffer some bleeding and discomfort, but that she would be able to leave the hospital in a day or two if there were no complications. He described the operation in a general way as consisting of the insertion of a surgical needle into her back in order to obtain a specimen of kidney tissue. He also indicated that the urologist, would perform the operation and would describe the details more fully. The only complication which Dr. N. mentioned was the possibility of considerable pain and bleeding for which surgery might be necessary. He did not discuss the alternative of an open biopsy, which would require an incision and would be conducted under general anesthesia, because he did not consider that procedure advisable. He never mentioned the danger that the plaintiffs gall bladder might be punctured during the operation, an injury which did in fact occur.

As the attending physician, Dr. N. admitted the plaintiff to the Greenwich Hospital on October 31, 1972. On the evening of November 2, 1972, the defendant urologist visited the plaintiff in her room at the hospital to discuss the operation to be performed the next morning. He told her that there might be some bleeding and that there was a risk of hemorrhaging and of losing a kidney. The alternative of an open biopsy procedure under a general anesthetic was not mentioned, although Dr. B. had performed such operations previously and conceded that it was a more controlled procedure in terms of visualizing the kidney. He did not consider this procedure to be a viable alternative for the plaintiff, however, because there is a greater risk of complications, especially those involving general anesthesia. After Dr. B. had departed, the plaintiff, in accordance with the rules of the hospital, signed a written form consenting to the surgical procedure which had been described.

The next morning the plaintiff was taken to a room in the x-ray department of the hospital where the urologist and a student nurse were in attendance. The defendant, the director of radiology at the hospital, was also present for the purpose of operating the fluoroscopic equipment which was necessary to provide a view of the kidney and the needle while the biopsy was being performed. The urologist explained the procedure, advising the plaintiff that she would lie prone upon an x-ray table with a pillow under her upper abdomen and that he would give her instructions throughout the procedure.

After the plaintiff had been placed upon the table, Dr. B. injected a local anesthetic into the kidney region by using a small gauge anesthesia needle. He then inserted the biopsy needle and, using the fluoroscopic screen between six and eight times, he located the kidney and extracted a tissue specimen. After examining the specimen he concluded that it was inadequate. He made a second attempt to obtain a piece of kidney tissue, advising the plaintiff beforehand and obtaining her consent. He adjusted the biopsy needle in order to obtain a deeper piece of kidney tissue and once again inserted it. In the course of this procedure the plaintiff suddenly felt pain far more severe than previously experienced and the needle was withdrawn before the tissue specimen could be obtained. During abdominal surgery on November 6, 1972, to determine the cause of the abdominal pain which the plaintiff continued to suffer following the biopsy procedure, it was discovered that her gall bladder had been punctured and it was removed.

The complaint was in two counts, the first being directed against the defendant hospital and the second against the three doctors who in some manner had been connected with the biopsy procedure. One of the specifications of negligence in each count was the failure "to obtain the plaintiffs intelligent and informed consent to the performance of a percutaneous renal biopsy."

I

The plaintiffs first claim of error involves the charge upon the absence of informed consent as alleged in the complaint, particularly with respect to the duty of a physician to advise a patient of feasible alternatives.[1] The court instructed the jury that the duty to give a patient all information material to the decision to undergo an operation includes the obligation to advise of feasible alternatives. The charge continued: "Now the duty to warn of alternatives exists only when there are feasible alternatives available. *An alternative that is more hazardous is not a viable alternative." [Emphasis added (by court)]* The plaintiff excepted to the italicized sentence of the charge as removing from the patient the decision of which alternative procedure was the least dangerous. The same charge was repeated in response to a request of the jury, after they commenced deliberations, for a further definition of the standard of care. Again the plaintiff excepted to that part of the instructions.

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[1] This portion of the charge was as follows:

"The theory of informed consent imposes a duty upon a doctor which is completely separate and distinct from his responsibility to skillfully diagnose and treat the patient's ills. A physician is bound to disclose all known material risks peculiar to the proposed procedure. Materiality is defined as the significance a reasonable person in what the physician knows, or should know, in his patient's position would attach to the disclosed risk or risks in deciding whether to submit or not to submit to the renal biopsy. It is the duty of the physician to give a patient whose situation otherwise permits it all information material to the decision to undergo the proposed procedure. And this duty also includes a duty of a physician to advise of feasible alternatives. Now, the duty to warn of alternatives exists only when there are feasible alternatives available. An alternative that is more hazardous is not a viable alternative. The burden is on the plaintiff to show not only an unjustified failure to disclose the risk of a proposed procedure, but also that such failure was the proximate cause of the plaintiffs injury."

We have not had previous occasion to consider substantively[2] the doctrine of informed consent as a basis for malpractice liability of a physician. In some of our cases, where the claim against the physician was contractual in nature, we have recognized the importance of informing the patient of certain aspects of the contemplated treatment or surgical procedure. . . . We have approved the principle that "[E]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault for which he is liable in damages." . . . [I]f the lack of consent was established, the removal of the moles was in itself a trespass and had the legal result of an assault." . . .

The theory of battery as a basis for recovery against a physician has generally been limited to situations where he fails to obtain any consent to the particular treatment or performs a different procedure from the one for which consent has been given, or where he realizes that the patient does not understand what the operation entails. . . . The failure to make a sufficient disclosure, which is ordinarily the basis for claiming lack of informed consent, has been regarded by most courts as presenting the question, not whether there was an effective consent which would preclude an action for battery, but whether the physician had fulfilled his duty of informing the patient under the appropriate standard. . . . Traditionally the standard was deemed to be one set by the medical profession in terms of customary medical practice in the community. . . . As in other aspects of medical science, only members of the profession are ordinarily familiar with the standard and deemed qualified to testify about it. . . .

The incongruity of making the medical profession the sole arbiter of what information was necessary for an informed decision to be made by a patient concerning his own physical well-being has led to various judicial and legislative attempts within the last decade to define a standard tailored to the needs of the patient but not unreasonably burdensome upon the physician or wholly dispensing with the notion that "doctor knows best" in some situations. While the essential ambivalence between the right of the patient to make a knowledgeable choice and the duty of the doctor to prescribe the treatment his professional judgment deems best for the patient has not been fully resolved, the outline has begun to emerge.

In a trilogy of cases decided in 1972 the traditional standard of customary medical practice in the community was abandoned by three jurisdictions as the criterion for informed consent in favor of a judicially imposed standard designed to provide a patient with information material to his decision upon a course of therapy. *Canterbury* v. *Spence,* 464 F.2d 772 (D.C. Cir.) cert. denied, 409 U.S.1064, 92 S. Ct. 564, 34 L. Ed. 2d 518 (1972); *Cobbs* v. *Grant,* supra; *Wilkinson* v. *Vesey,* supra. The formulations of the disclosure standard in these cases vary. "Thus the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked." . . . "The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is whatever information is material to the decision." . . . "It is our belief that, in due deference to the patient's right to self determination, a physician is bound to disclose all the known material risks peculiar to the proposed procedure." . . . These decisions require something less than a full disclosure of all information which may have some bearing, however remote, upon the patient's decision. . . . Although the test is phrased in terms of the "patient's need," rather than impose on the physician an obligation to disclose at his peril whatever the particular patient might deem material to his choice, most courts have attempted to frame a less subjective measure of the physician's duty. "[N]o less than any other aspect of negligence, the issue on nondisclosure must be approached from the viewpoint of the reasonableness of the physician's divulgence in terms of what he knows or should know to be the patient's informational needs." . . . "Materiality may be said to be the significance a reasonable person, in what the physician knows or should know is his patient's position, would attach to the disclosed risk or risks in deciding whether to submit or not to submit to surgery or treatment." . . . In states which have legislated this so-called "lay" standard of disclosure vis-a-vis the orthodox professional standard, the statutes typically impose a duty to disclose such information as a "reasonable patient would consider material to the decision whether or not to undergo treatment or diagnosis." . . .

The standard has been further delineated by specifying various elements which the physician's disclosure should include: "(1) the 'nature' of the procedure, (2) the 'risks' and 'hazards' of the procedure, (3) the 'alternatives' to the procedure, and (4) the anticipated 'benefits' of the procedure." . . . "Obviously there is no need to disclose risks that are likely to be known by the average patient or that are in fact known to the patient usually because of a past experience with the procedure in question." . . . Some limited recognition has been given also to the therapeutic privilege of a physician to withhold information where disclosure might jeopardize a course of therapy. ...

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[2] In *Keenan* v. *Yale New Haven Hospital,* 167 Conn. 284, 285, 355 A.2d 253 (1974), we held that an amendment to a malpractice complaint stating that a physician had "assaulted the plaintiff by performing a surgical operation on him without securing his *informed consent"* stated a cause of action separate and distinct from the negligence originally pleaded, did not relate back to the date of commencement of the action and was, therefore, barred by the applicable statute of limitations, General Statutes § 52-584. *[Emphasis added.]*

The leading case of *Canterbury* v. *Spence,* supra, was given a generally favorable reception by the judiciary, and soon the lay standard of disclosure had been adopted in eight states,[3] obligating the physician to provide the patient with that information which a reasonable patient would have found material for making a decision whether to embark upon a contemplated course of therapy. ... Three of these states subsequently have abandoned this standard by statutes which expressly or implicitly adopt the professional standard of disclosure in accordance with the practice of a reasonable medical practitioner under similar circumstances. ... Despite the possibility of legislative revision, we are persuaded that criticism of the professional standard as expounded in *Canterbury* is well-founded and **we, therefore, shall follow the lay standard of disclosure.** *[Emphasis added. Ed.]*

This standard was the basis for the charge given by the trial court upon informed consent.[4] As we have noted, the plaintiff takes issue only with the single sentence of that charge which declares "[a]n alternative that is more hazardous is not a viable alternative.' During the trial there was considerable testimony about the hazards of the needle biopsy, which had resulted in puncturing the plaintiff's gall bladder, as compared to an open biopsy requiring general anesthesia and a surgical incision. ..., a urologist called by the plaintiff, testified that the alternative of an open biopsy should have been discussed with the plaintiff with disclosure of the risks attending any surgical procedure conducted under general anesthesia. Three doctors presented by the defendants testified that an open renal biopsy was not a viable alternative to a needle biopsy. Another witness for the defendants, ..., a physician, testified that an open biopsy was more hazardous than a needle biopsy, but that he did inform his patients that the alternative of an open biopsy was available with its attendant risks, though he advised against it. It was conceded that an open biopsy alternative was never discussed with the plaintiff who, with the benefit of hindsight, testified that she would have chosen that procedure if she had known of it.

The instruction that an alternative which is more hazardous is not viable and, therefore, need not be mentioned to the patient has the effect of limiting the physician's duty to disclosure of only the least hazardous procedure available, presumably the one contemplated. The issue then becomes, not whether the patient has been informed of viable alternatives, but whether the doctor has recommended the least dangerous of them, because those which are more hazardous need not be discussed. This instruction, therefore, wholly relieves physicians of any obligation to discuss alternatives with their patients and substitutes merely a duty to recommend the safest procedure. It is incompatible, therefore, with the view which the trial court expressed in the remainder of the charge that the patient must be provided with sufficient information to allow him to make an intelligent choice.

The defendants have not attempted to defend or to cite any authority in support of the proposition that if an alternative is more hazardous it need not be disclosed, although its source appears to have been one of their requests to charge. They contend (1) that there was overwhelming evidence that an open kidney biopsy was not a viable alternative to a closed needle biopsy; (2) that, because of the plaintiff's previous education and employment as a medical assistant to a physician, she was far more sophisticated in medicine than most patients; and (3) that the questioned sentence of the charge did not sufficiently distort the total effect of the charge, which has otherwise favorable to the plaintiff, so as to be prejudicial. We disagree. The plaintiff did produce at least one doctor who testified that an open biopsy was a viable alternative and the jury could reasonably have believed him rather than the several experts who testified for the defendants. The jury could also have found that the plaintiff had insufficient medical knowledge to be aware of the open biopsy procedure as a viable alternative for her. It is true, of course, that "a charge to the jury is to be judged in its entirety and harmful error cannot be predicated on detached sentences or portions of the charge unless it is reasonably probable that the jury could have been misled by them." ... Although we are reluctant to find reversible error because of a single sentence of a lengthy charge, we are unable to avoid the conclusion that the error was probably harmful. The major focus of the testimony on the issue of informed consent was the relative hazard involved in each of the two medical procedures. In advising the jury that more hazardous alternatives were not viable and could be withheld from the patient, the trial court invited them to decide the issue of informed consent simply by comparing the risks of the two procedures. The jury could well have understood that, if they concluded that an open biopsy was more hazardous than the needle biopsy performed, there was no duty to inform the plaintiff of that alternative. Such a misunderstanding would have been wholly inconsistent with the view we have adopted requiring that all viable alternatives be disclosed even though some involve more hazard than others.

II

The remaining claims of error in the charge relate to the instructions upon (1) evaluating the opinions of expert witnesses, (2) the application of the legal principles to the evidence, (3) the liability of a physician for "a bona fide error in judgment," and (4) the extent of the area to be considered in determining the applicable standard of care.

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[3] California, Louisiana, New York, Ohio, Pennsylvania, Rhode Island, Vermont and Washington.

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[4] See footnote 1, supra.

A

The trial court charged that, in evaluating the answers given by expert witnesses to hypothetical questions in which certain facts are assumed, the weight of the expert opinion would depend upon whether the postulated facts had actually been proved. In excepting to the charge, the plaintiff conceded the accuracy of this instruction but requested a further instruction that the jury should also consider the sufficiency of the facts assumed in the hypothetical question in weighing the opinion. The court did not make the suggested revision of the charge.

We have approved a jury instruction upon the evaluation of expert testimony which directs attention both to the omission of material facts from a hypothetical question as well as the evidentiary basis for the facts assumed. *Pischitto* v. *Waldron,* 147 Conn. 171, 176, 158 A.2d 168 (1960). Although the trial court should have amplified this portion of the charge in accordance with the plaintiff's exception, we are not persuaded that the failure to do so was substantially harmful. *Matthews* v. *F.M.C. Corporation,* 190 Conn. 700, 705, A.2d (1983); *Siladi* v. *McNamara,* 164 Conn. 510, 515, 325 A.2d 277 (1973); *Amato* v. *Desenti,* 117 Conn. 612, 617, 169 A. 611 (1933).

B

The plaintiff's claim that the charge made insufficient reference to the evidence to serve as an adequate guide to the jury is not supported by our review. In part the plaintiff relies upon the failure of the court to grant approximately ten pages of her voluminous request to charge which summarize the evidence presented from her understandably partisan viewpoint. The charge was more than a bare statement of the applicable legal principles and did include a detailed explanation of the pleadings with various references to the evidence. See Practice Book § 318. The claims of negligence were discussed with specific reference to the defendants to whom they related.

The plaintiff claims there should have been a further "marshaling" of the evidence in response to several notes submitted by the jury during their deliberations. These inquiries consisted of requests for the definition of certain words, for the testimony of some witnesses, and, as construed by the court, for another reading of the charge upon the standard of care. Compliance with the plaintiff's demand under these circumstances would have been inappropriate.

"The degree to which reference to the evidence may be called for lies largely in the discretion of the court." . . . We conclude that the charge was not so deficient in this respect that it failed to serve as an adequate guide to the jury. . . .

C

In response to an exception, taken by counsel for the defendant B., that a portion of his request to charge had been omitted, the court corrected the initial charge as follows: "The part I left out is that he is not liable for a bona fide error in judgment provided he concludes, as best he can, and does what he thinks best, after a careful examination, and acts in good faith subject to the rule of care, skill and diligence such as I have defined it to you."[5] The plaintiff had objected before the recharge that the omitted portion of the request relating to bona fide error was a mere "appendage," that the initial charge had covered the subject adequately, and that a further charge upon the matter would unfairly emphasize that aspect of the case. Neither at that time nor in her exception after the corrected charge had been given did the plaintiff claim, as she does on this appeal, that the instruction relating to a "bona fide error in judgment" was an incorrect statement of the law.

The apparent source of the challenged language was a passage in *Green* v. *Stone,* 121 Conn. 324, 330, 185 A.72 (1936), as follows: "The plaintiff complains of the failure of the court to charge in the language of this request and of its statement in a single sentence of the charge that a doctor is not liable for a bona fide error in judgment, and says that the jury may well have obtained the impression from the charge that the defendant could under no circumstances be held responsible for an error of judgment so long as it was bona fide. The court repeatedly charged the jury that it was the duty of the defendant to exercise the care and skill required of a specialist in the field of obstetrics, and the charge made it abundantly clear that he would be absolved from a bona fide error in judgment only in case he exercised such care and skill." We do not construe *Green* as approving the reference to "a bona fide error in judgment" but as concluding that it did not sufficiently distort the general purport of the charge to constitute reversible error. A similar charge was also sustained in *Levett* v. *Etkind,* 158 Conn. 567, 576, 265 A.2d 70 (1969), although it is not clear that the portion pertaining to a "bona fide error in judgment" was under attack. We agree with the plaintiff, nevertheless, that to use such a phrase in a charge upon negligence serves only to confuse a jury by implying that only an error in judgment made in bad faith can be actionable. The central issue in the ordinary negligence case is whether the defendant has deviated from the required standard of reasonable care, not his mental state at the time of the conduct which constitutes the deviation. "Negligence is conduct which creates an undue risk of harm to others." . . . Errors in judgment which occur with the best intentions constitute negligence if they result from a failure to use reasonable care.

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[5] This portion of the charge was as follows: "The Court: The part I left out is that he is not liable for a bona fide error in judgment provided he concludes as best he can, and does what he thinks best, after a careful examination, and acts in good faith subject to the rule of care, skill and diligence such as I have defined it to you. If he exercises reasonable care, skill and diligence the fact that a result has not been as favorable as hoped for by the plaintiff or the physicians themselves raises no presumption of want of proper care or skill. In other words, if the physicians use skill, care and diligence they are not to be held liable if a bad result occurs. Failure in a procedure, bad results or injuries, as in this case, does not by itself raise any presumption of such want of skill or care."

We need not decide whether the allusion to nonliability of a physician for a bona fide error in judgment was sufficiently confusing in the context of the whole charge to create the likelihood of a misunderstanding on the part of the jury. . . . As we have indicated, the ground for the plaintiff's present attack on this portion of the charge was not included in the exception taken in the trial court. . . . We are not bound to consider a claim unless it was "distinctly raised at the trial . . ." The plaintiff, therefore, cannot prevail upon this ground which was first raised on appeal.

D

The plaintiff's final claim of error with respect to the charge is that the court instructed the jury that the applicable standard of conduct was the standard of practice of doctors in the same specialties practicing in the State of Connecticut.[6] The plaintiff excepted to this geographical limitation of the applicable standard as being arbitrary.

In *Geraty* v. *Kaufman,* 115 Conn. 563, 574, 162 A.2d 33 (1932), we rejected the notion that a physician was obliged to exercise only that degree of skill possessed by other practitioners in the community in which he lived and held that testimony of the general practice in this state concerning the particular medical procedure involved was properly admitted. "There is now no lack of opportunity for the physician or surgeon in smaller communities to keep abreast of the advances made in his profession, and to be familiar with the latest methods and practices adopted." Id. We reaffirmed the view that "the general neighborhood is the entire state of Connecticut" in *Fitzmaurice* v. *Flynn,* 167 Conn. 609, 617, 356 A.2d 887 (1975). There we recognized that "there may exist reason to disregard territorial limitations even with regard to state boundaries," but found no need then to decide that question. Id. We also limited our definition of the general neighborhood to the boundaries of this state in *Katsetos* v. *Nolan,* 170 Conn. 637, 646, 368 A.2d 172 (1976), again finding no necessity to decide whether that restriction should be expanded.

In the present case no evidence was offered of standards of practice for any of the specialties involved different from those prevailing in this state. The plaintiff's expert witness, . . . , practiced urology in New York City and had taught at medical colleges in that city. He testified that the standard of care for the performance of a renal biopsy was the same throughout the United States. He was permitted to testify fully as to the applicable standard both for performance of such biopsies and for obtaining informed consent thereto. A physician, . . . , called by one of the defendants, also testified that the standard of care for performance of a closed renal biopsy was the same in New York, where he practiced as a urologist, as in Connecticut. In view of this testimony we are not persuaded that the plaintiff was harmed by the limitation of the standard of care to medical practice within this state.

We must, nevertheless, face the issue since it may well arise upon the retrial of the issue of informed consent which we have ordered. **We think the time has come to broaden the geographical limitation we have previously imposed to include the entire nation.** *[Emphasis added. Ed.]* Under contemporary conditions there is little reason to retain this vestige of former times when there was a substantial basis for believing "that the rural doctor should not be held to the standards of the urban doctor, since the latter had greater access to new theories and had more opportunity to refine his method of practice." *Fitzmaurice* v. *Flynn,* supra, 617. We are not aware of any differences in the educational background and training of physicians practicing in Connecticut compared with those in other states. Medical literature of significance is normally disseminated throughout this country and not confined to a particular state. We align ourselves with many other jurisdictions which have in recent years abandoned similar geographical restrictions in medical malpractice cases. . . .

III

We must next consider the plaintiff's claim that the court erred in directing verdicts for the defendant, the radiologist who participated in the operation, and the defendant hospital. It is undisputed that his role was to operate the fluoroscopic equipment in order to enable the urologist performing the operation, to see the plaintiff's kidney and the needle used to accomplish the biopsy. Because it was impossible to manipulate the biopsy needle while the fluoroscopic screen was in a position to provide visualization, the device had to be moved in and out of that position during the course of the procedure at the request of the operating surgeon. D.'s function was to respond to these requests by controlling the movement of the screen through the use of the related machinery. There is no evidence that he did not perform this task properly and in accordance with the appropriate standard for his specialty. He played no part in discussing the procedure with the plantiff and there was no evidence that his duty as a radiologist required his participation in obtaining her informed consent. None of the specifications of negligence,[7] which are addressed indiscriminately to the three physician defendants N., B. and D., pertain to the performance of the duty of a radiologist as established by the evidence in this case. The court properly directed a verdict in favor of the defendant D.

With respect to the defendant hospital, the claim of liability predicated upon the alleged negligence of the defendant D. as an employee acting within the scope of his employment must fall with our disposition of the claim against him personally. There was no evidence which would justify submission of the remaining allegations of corporate negligence[8] to the jury. No testimony was presented to indicate that reasonably prudent hospital practice imposed any duty upon this defendant to supervise the physicians who participated in the operation in any of the respects claimed. We find no error in the direction of a verdict for the defendant hospital.

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[6] In the initial charge the court referred to the "standard of practice of doctors in the same specialties practicing in the same general neighborhood," leaving the determination of what constituted the general neighborhood to the jury. After an exception, in which counsel for one of the defendants cited *Katsetos* v. *Nolan,* 170 Conn. 637, 646, 368 A.2d 172 (1976), the court recharged that the general neighborhood was the entire state of Connecticut.

IV

We are also convinced that the trial court should have granted the motion of the defendant N. for a directed verdict. Since he did not participate in the kidney biopsy operation, the claims of negligence in the performance of that operation were inapplicable to him. The trial court recognized that there was no evidence that he was involved in conducting the surgical procedure and therefore, limited the basis for holding him liable to the allegation of failure to obtain an informed consent.

Although it is undisputed that N. did discuss the kidney biopsy with the plaintiff and describe the procedure generally, there was no evidence that it was his duty to do so. In fact, the testimony indicated the contrary. The plaintiff's expert witness, . . . testified that an internist, such as N., had no obligation to discuss the surgical procedure with the plaintiff or to obtain her informed consent. He stated unequivocally that those duties rested upon the physician who was to perform the operation. The defendant B. testified to the same effect and also said that in fulfilling his responsibility to obtain an informed consent he had not relied upon any discussion N. may have had with the plaintiff.

The principle that one who gratuitously undertakes a service which he has no duty to perform must act with reasonable care in completing the task assumed is not applicable to this situation. . . . Although N. did describe the general nature of the operation to the plaintiff and some of the possible complications, he also told her that a more detailed explanation would be provided by B., the urologist. There is no evidence that his reliance upon the operating surgeon to provide the information necessary for informed consent was contrary to normal medical practice or was unreasonable under these particular circumstances. With respect to the failure to discuss the open biopsy alternative, which is the single omission claimed by the plaintiff in the explanation given, it would have been presumptuous for N., an internist, to suggest a surgical procedure in the field of urology other than that which B., a qualified specialist in that area of medicine, had recommended and thus possibly undermine the confidence the plaintiff should have in her surgeon. We hold that under the circumstances of this case N., as the referring physician, had no obligation to inform the plaintiff of viable alternative procedures but might reasonably have relied upon B., the specialist, to provide such information. We shall not, therefore, disturb the verdict in favor of N.

VI

In summary, we have found reversible error only *[Emphasis added. Ed.]* in the portion of the jury charge stating that a physician need not discuss with a patient any alternative which is more hazardous than the treatment he has recommended. That error infects only the theory of the complaint based upon a failure to obtain an informed consent. The necessity for a new trial, therefore, is limited to that issue and to the defendant B., whose sole duty it was to provide the requisite information to the plaintiff. . . .

The defendants N. and B. have included in their briefs a "counterstatement of issues," claiming essentially that the general verdict doctrine is applicable to this case because the jury may have concluded that the various complications which the plaintiff suffered after the kidney

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[7] The second count of the complaint, which was addressed to the individual physician defendants, contained the following paragraphs:

"26. The injuries and damages suffered by the plaintiff as hereinbefore stated were caused by the negligence and lack of skill and care of the defendants B., D. and N.

"a. In that they failed to obtain the plaintiff's intelligent and informed consent to the performance of a percutaneous renal biopsy;

"b. In that they failed to accurately determine the location, size, configuration and stability of the plaintiff's right kidney before attempting the needle biopsy;

"c. In that they failed to accurately examine and analyze the specimen from the biopsy needle after the first attempt to determine whether or not kidney tissue was obtained;

"d. In that during the biopsy procedure they failed to determine the location, size, configuration and stability of the plaintiff's right kidney in relation to the biopsy needle;

"e. In that they failed to allow for the effect of the plaintiff's respiration on the location and stability of the plaintiff's right kidney during the biopsy procedure;

"f. In that they failed to accurately examine and analyze the specimen from the second biopsy attempt to determine the nature of the tissue obtained; and

"g. In that they performed upon the plaintiff a percutaneous needle biopsy to obtain a specimen of kidney tissue, which procedure in itself constitutes a violation of the required standard of care."

[8] The first count of the complaint, which was directed only to the defendant hospital, contained the following paragraphs:

"25. The injuries and damages suffered by the plaintiff as hereinbefore stated were caused by the negligence and lack of skill and care of the defendant Greenwich Hospital Association, acting through its agent and employee the defendant D. as more particularly described hereinafter, and such corporate defendant was further negligent:

"a. In that it failed to reasonably require the use of fluoroscopic visualization during the performance of the percutaneous needle biopsy;

"b. In that it failed to require the analysis of the results of the percutaneous needle biopsy within a reasonable time after its completion;

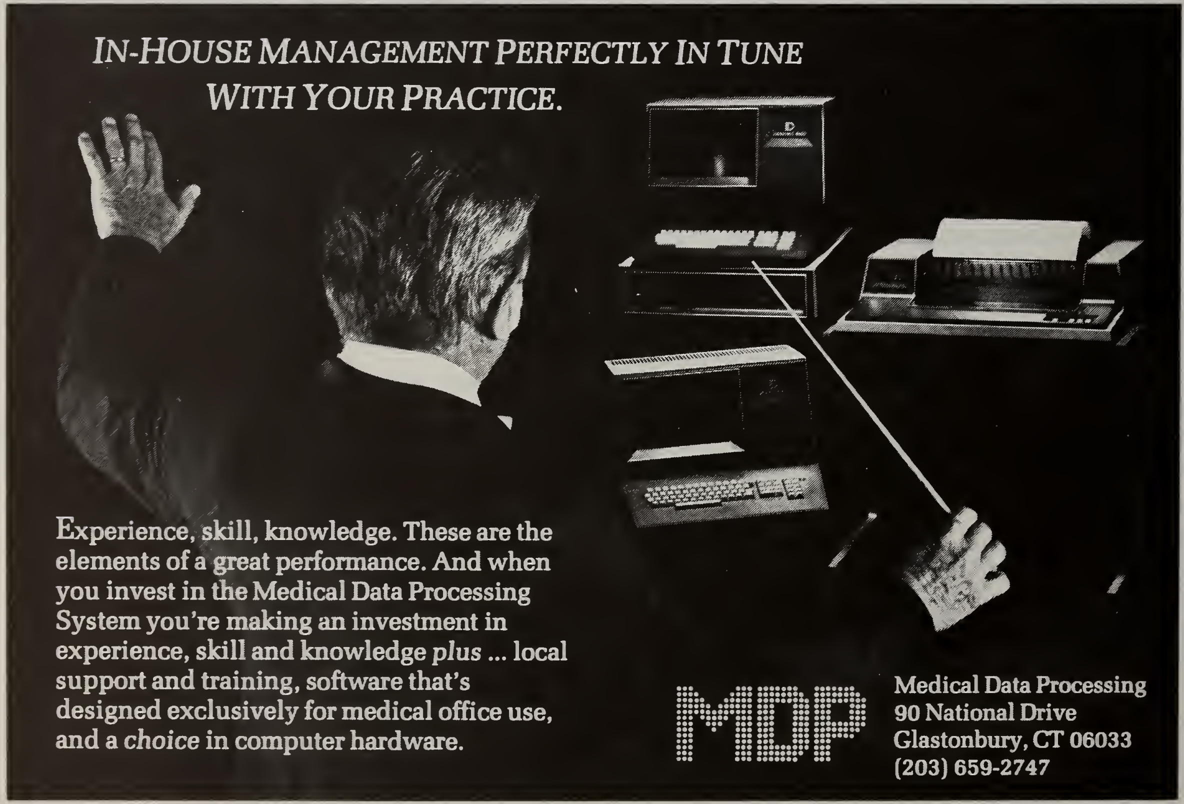
"c. In that it approved of and permitted the performance of a percutaneous needle biopsy to obtain a specimen of the kidney tissue, which procedure, in and of itself, constituted a violation of the required standard of care;

"d. In that it failed to obtain the plaintiff's intelligent and informed consent to the performance of a percutaneous renal biopsy."

biopsy operation were not causally related thereto. The defendants have failed to follow Practice Book § 3012 (a), which requires an appellee to file a preliminary statement of issues where he "wishes to present for review alternate grounds upon which the judgment may be affirmed . . ." We have not previously insisted upon compliance with that provision, however, where the general verdict rule is clearly applicable. *Batick* v. *Seymour,* 186 Conn. 632, 639, 443 A.2d 471 (1982). Here the claim that the jury's verdict may have been based wholly on a finding that no damages were proved by the plaintiff borders on the frivolous. It was virtually undisputed that her gall bladder was punctured during the biopsy and had to be removed. Furthermore, we have never extended the doctrine to a verdict for a defendant which might possibly rest upon a determination of the damages issue against a plaintiff nor are we inclined to do so.

There is error in the resolution of the claim against the defendant for his alleged failure to obtain the informed consent of the plaintiff; that judgment is set aside and the case is remanded for a new trial of that issue as well as the related question of damages against the defendant B., there is no error with respect to the other issues or the other defendants.

In this opinion the other judges concurred.



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Prospective Payment and Rising Health Costs

TIMOTHY B. NORBECK

There are several items on which I could report but I ask your indulgence so that I may speak a little longer than usual to discuss the All-Payer legislation, the present legislative climate and rising health care costs and the peoples' perception of the problem.

As you are all aware, the CSMS opposed the All-Payer, prospective payment legislation for hospitals during the current legislative session which concludes today. In the beginning, we were joined in our opposition to the bill by Blue Cross/Blue Shield and the Connecticut Hospital Association. Toward the end, their opposition was reduced to tacit approval and we were left alone to take on the business community, the insurance industry, the Governor, organized labor, the Commission on Hospitals and Health Care, and the General Assembly.

Blue Cross/Blue Shield and the CHA were under tremendous pressure and were able to negotiate financial considerations to the extent that they agreed to withdraw their opposition to the legislation. Such agreement however, should not be construed as support for the bill, as the CHA still has many reservations about it.

While I believe that we put up a very good fight against a very formidable array of opponents and against all odds, and despite the fact that we were on the side of the angels, the bill passed.

Why did Connecticut move to pass such legislation and why are other states moving in the same direction. At the recent AMA Leadership Conference, the following reasons were suggested:

1. The medicaid budget is the fastest growing budget item in all 50 states.
2. The state itself is a big employer and its health insurance premium costs are mounting.
3. States are worried about employers leaving the state—businesses are complaining to state governments about the burden of increased health care costs and the legislators are listening.
4. States are complaining that the federal government hasn't done anything to arrest the growth of health care costs and therefore are seizing the initiative themselves.

In addition, surveys indicate that almost half of the American people believe that the cost of health care is one of the three most important national issues facing the country today, and 65% of them believe that physicians contribute "a great deal" to rising costs. A recent poll commissioned by the American Association of Retired Persons (AARP) indicates that 72% favor the state or federal government imposing controls on hospital and physician charges. Somewhat shocking was the revelation that 53% believed that such controls could be achieved and costs contained *without* affecting the quality of care. Clearly we all have much work ahead of us in apprising the American public and perhaps, especially our elderly, the reasons for escalating health care costs.

Major league baseball players averaged $250,000 for seven or eight months of work back in 1981, and yet went out on strike for more benefits. They now average $340,000 for those seven or eight months of work. In addition, they can draw a paid pension of $46,000 a year at age 65 after only 10 years of service. Yes, indeed, perhaps the time *is* out of joint as Shakespeare's Hamlet observed centuries ago. People may not object too vigorously to such salaries for sports figures, but they remain critical of trained physicians who average less than a third of the major leaguers and have far greater responsibilities. Somehow we must find a way to inform the public the reasons for our escalating health care costs. Perhaps an opportune moment with every patient, particularly the elderly, might be in order.

I'd like to outline briefly for you the reasons we used in objecting to the All-Payer bill, and they are also germane to our general problem of rising health care costs and our need to better publicize such reasons. If we don't, there will be more pressure brought to bear on

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TIMOTHY B. NORBECK, Executive Director of the Connecticut State Medical Society.

This speech was presented by Mr. Norbeck at the 192nd Annual Meeting of the Connecticut State Medical Society on May 9th, 1984 at the Parkview Hilton Hotel, Hartford, CT.

physicians, not to mention the possible imposition of DRGS in physician's offices.

The Council of the CSMS determined that imposition of a prospective payment system in Connecticut might well and probably would impair the quality of hospital care in this state. Many times we asked but never received an answer to the question—why should Connecticut be the fifth state to enact such a system when the reason for imposing it in the other four states—N.Y., N.J., M.D., and Mass.—was that their hospital costs were *considerably* greater than not only the national average but also the New England average. In stark contrast to NY, NJ, MD and MA, in Connecticut we have fewer beds, fewer admissions, fewer surgical operations, a shorter length of stay and lower hospital expenses per capita—and these figures are below both the national and New England average. We argued that businesses and the insurance industry wanted to pay less for everyone's hospital benefits and that less cost would mean less care—that there were incentives in the bill to ration care and no quality safeguards—that Commissioner Wright of the Commission on Hospitals and Health Care might well be referred to in the future as Czar Wright for the prerogatives granted him in the legislation.

When we discussed our objections to the legislation with the media, we were always asked, "but, what about rising health care costs?"

Here is how we answered that question. Naturally all physicians, the CSMS and others are concerned about the increase in health expenditures. But let us remember that there are many good reasons for the escalation. One point which we have attempted to stress is that health care is a unique service. If one had his or her house painted five years ago and then again today, the cost would have gone up considerably for this service—yet the product (paint) and the service itself or the labor have not changed over those years. Captious critics gleefully denounce medicine for its role in rising health care costs but are careful to avoid informing the public as to the real reasons for such an escalation. The public has been misled in this effort by its failure to recognize that achievements in medical technology and, in more than a few cases, bonafide medical miracles, although very expensive, potentially impact on and benefit every citizen. Medical technology, of course, is constantly changing, and the development of ultrasound, scanners, radioisotopes, fiber optics and nuclear magnetic resonance have greatly enhanced the ability of physicians to diagnose an illness. Transplant surgery, coronary bypass operations, more sophisticated treatment for burn victims, and the new scanners cost a great deal of money but also help our system to save lives and enable people to live longer, more productive lives. Critics claim that we have too many scanners in the United States, but Japan has just as many with a population half as large as ours. And a recent National Institutes of Health consensus panel concluded that the United States has *too few* machines.

The death rate from coronary artery disease is down by 25% over the past 12 years, a very encouraging statistic, but such progress costs money. Advanced technology and 100,000 plus coronary bypass operations per year at a cost of $15,000-$20,000 per operation have been instrumental in that success. Some 250,000 Americans owe their improved quality of life to pace makers and about 65,000 get artificial hip joints every year. The kidney dialysis program began in 1972 and was budgeted for $250 million. Today that bill exceeds $2 billion and represents countless more recipients living better lives.

Some people complain that health care costs are now over 10% of our gross national product and that such a figure is excessive. If, as Disraeli stated, "the health of the people is really the foundation upon which all their happiness and all their powers as a state depend." then how much of the gross national product should our nation be spending on health? Our Gross National Product is nothing more, really, than an indicator of a nation's wealth. We all share a concern over rising costs, but who is to say that 10% constitutes too much for this country?

And then we received the inevitable question about the escalation of physicians' fees. As Michael DeBakey, M.D. and Lois DeBakey, Ph.D, have noted, the national Consumer Price Index for the past five years shows an average annual increase in living costs of 9.8%, whereas the average increase for physicians' services was 9.7%—despite rapidly escalating malpractice premiums.

Demography also plays a significant role in rising health care costs. Although constituting merely 11% of our national population, our 65 and over group accounts for one-third of all health care expenditures. The 65 and over group is expanding by 500,000-750,000 each year—attesting to the good medical care they receive. This is not to blame anyone. We should rejoice at such figures and recognize that such costs are to be expected. Of all the people in the history of the world who have lived to be 65, half are still alive today.

It has been estimated by The American Cancer Society that smoking alone accounts for 350,000 premature deaths in the United States each year. The elimination of smoking would also reduce the cost of medical care by 11%. A recent study of the hidden costs of cigarette smoking conducted by Policy Analysis, Inc. and released at an American College of Cardiology meeting in Dallas indicated that a middle-aged man who smokes heavily can expect to spend an average of $59,000 in extra medical bills and lost earnings in his lifetime. It was also pointed out that the study's cost estimates probably were low because it considered only smoking's contribution to lung cancer, heart disease, and emphysema.

Perhaps businesses, which of late have been so critical of our health system and its rising costs, might pitch in and attempt to alleviate the problem. Business groups in the Omaha, Nebraska area formed The Wellness Council of the Midlands (WELCOM) whose sole purpose is to "promote wellness programs at the work site." A spokesman for the group has said that "the problem is us. On balance, too many Americans are afflicted with health problems that are directly related to their freely chosen lifestyles." As was reported in the April, 1984 issue of *Nations Business,* the group stated "that as more employers offer quality programs, not only will more individuals benefit, but spiraling costs of health care can be better contained." This approach certainly makes more sense than to prematurely rush into an unproven and untried prospective payment system. The Government estimates that from 50%-65% of all health care expenditures are directly attributable to accidents and illnesses related to life style abuses such as smoking, drinking and eating too much and exercising too little. If we want to keep up with growing technology without cutting back on quality, perhaps we will all have to develop better health habits in the work place and home. The *unacceptable* alternative could be to ration care as in Great Britain, where they have systematically written off their elderly—where there is no kidney dialysis available to those over 62—where five year delays for hip replacements are not uncommon and *where* transplants and coronary artery bypass operations *won't* be performed on patients 55 years of age or older.

Those of you who read Joseph Califano's column in the Sunday *New York Times* noted that Mr. Califano is calling for a national commission to reform health care. This and other such measures certainly will have an adverse impact on the quality of care. The issue seems to be on everyone's mind these days.

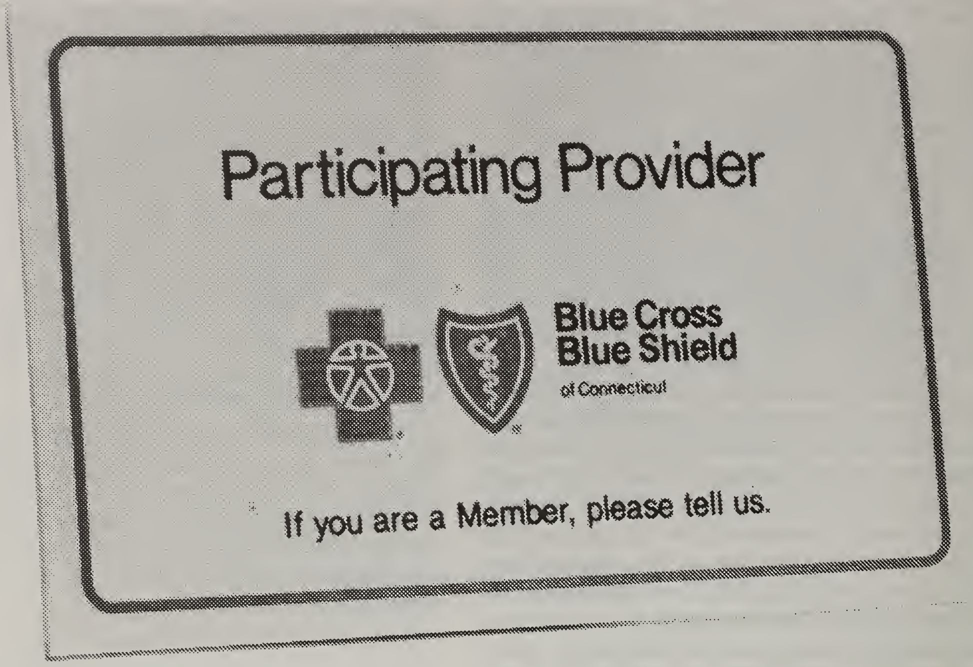
Getting back to the All-Payer Prospective Payment Bill, it probably won't even contain hospital costs. In New Jersey under a similar program, hospital costs continue to escalate despite a DRG system imposed in 1980. And under a similar scheme in Massachusetts, some 3,000 hospital workers were laid off after the first year.

There were many political pressures brought to bear in Connecticut this session and proponents of the legislation promised that the measure would lower costs and maintain quality. It has been rumored that between $500,000 and $700,000 were spent over the past few months to promote the bill. The combined might of the business community and the insurance industry plus their potent political action committees helped to ensure passage of the bill. We pointed out that this legislation lacked quality safeguards and probably wouldn't even curtail the growth of hospital costs.

Some have asked why CSMS continued to oppose the bill when all other parties either supported it or withdrew their opposition. The Council of the CSMS believed that this legislation jeopardized patient care in hospitals and felt it was important to stand on principle and oppose the bill *regardless* of the odds or the opponents.

Well, the All-Payers DRG system will soon be the law of the state and will be eventually implemented in all of our community hospitals. If the system results in *in*sufficient care being made available to your patients, it is important to understand that they will *not* be blaming the Governor or their legislators; they will be blaming you and the hospital.

Therefore, even though the legislature rejected CSMS amendments for physician monitoring and control of the new system, it is important that you closely maintain the physician's proper role as the director of the patient's treatment, and in particular, as the patient's advocate against the pressures of institutional administration. Whether or not the new system works, at least people can become more and more certain as time goes by, that *their* physicians, at least, are on *their* side.



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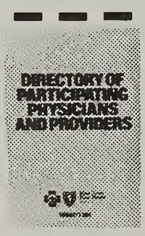

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Nicotine Chewing Gum

ALEX A. CARDONI, M.S. PHARM.

Recently, Merrell-Dow introduced the first prescription chewing gum dosage form (Aspergum is non-prescription!). It is called Nicorette R and it contains a nicotine resin complex in a buffered chewing gum base. It was designed for use by smokers who wish to stop smoking cigarettes. In the words of the manufacturer, "Nicorette is indicated as a temporary aid to the cigarette smoker seeking to give up his or her smoking habit while participating in a behavioral modification program under medical supervision."

Pharmacology

Nicotine is a ganglionic stimulant which, until now, has had no role in therapeutics. It has both stimulant and depressant actions in the body, depending on the amount ingested. Peripherally, nicotine causes initial stimulation, then depression of all autonomic ganglia. At low dosage, nicotine stimulates the CNS and can produce tremor and increased respirations. At higher doses, the CNS is depressed and respirations become depressed. It can cause vomiting and stimulates the release of ADH. Cardiovascular effects include increased heart rate and increased blood pressure. The motility of the GI tract is increased with nausea, vomiting, and diarrhea.

Pharmacokinetics

Nicotine is rapidly absorbed via the lungs and through the buccal mucosa and is 80-90% metabolized, primarily to cotinine. Metabolites are eliminated in the urine. Nicotine crosses the placenta and is excreted in the milk of lactating women.

Chewing gum was selected as the dosage form because of efficacy and safety considerations. A tablet or lozenge would release a bolus dose of nicotine which would be potentially toxic. It seems, however that this problem could be overcome with the use of a sustained-release solid dosage form. I found no mention of this option made by Merrell-Dow.

The nicotine resin complex, incorporated into a chewing gum base is supposed to provide uniform release of nicotine when chewed, but should prevent rapid release of nicotine if *intact* gum is swallowed, for example, by a child. One potential problem that I see is that the rate and extent of release of nicotine will vary from smoker to smoker depending on the chewing characteristics of the individual smoker. It's likely to vary within a given smoker as well, as chewing characteristics probably vary within an individual depending on emotional state, extent of fatigue, and other factors.

The other reason for the chewing gum dosage form, according to the manufacturer, is that buccal absorption produces greater bioavailability of nicotine than does oral absorption, as significant hepatic first-pass metabolism after absorption from the GI tract reduces some of its "kick." Again, these same results could be achieved with a sustained-release solid dosage form. Good bioavailability from the gum dosage form has been documented (Russell, *et al.*, 1976; McNabb, *et al.*, 1982).

Clinical Use

The efficacy studies conducted with the gum confirmed the impression that smokers who have a high degree of nicotine dependence are most likely to benefit from its use. It provides nicotine blood levels sufficient to alleviate withdrawal symptoms in smokers who want to stop smoking. Thus, they can concentrate on the behavioral aspects of withdrawing from cigarettes while postponing withdrawal from nicotine itself.

Short-term comparative efficacy studies of the gum versus placebo showed that smokers who switched from cigarettes to the gum had significantly less irritability, anger, difficulty concentrating, restlessness, and impatience than those who used a placebo gum (Hughes, JR, American Psychiatric Association Meeting, New York, 1983).

ALEX A. CARDONI, M.S. Pharm., Associate Professor of Clinical Pharmacy, School of Pharmacy, The University of Connecticut Health Center, Farmington, CT.

The Drug Information Service is available free of charge to all health professionals in Connecticut. If you have a patient-specific question or a general question call M-F, 8 AM to 5 PM, 674-2782.

The pivotal efficacy study in this country was conducted by Christen and colleagues at the Indiana University School of Dentistry. In this study, the effects of 2 mg of nicotine resin complex on oral soft tissues were evaluated as well as short-term smoking cessation rates at 6 and 15 weeks. Oral health parameters were unremarkable with essentially no difference between the active gum and placebo regarding gingivitis, plaque, calculus, and staining. The 15 week "quit" rates were 12.4% for active gum and 4.8% for placebo.

Additional long-term (6-12 months) studies conducted in Sweden and England (Fagerstrom, KO, 1982; Jarvis, MJ, *et al.*, 1982) confirmed the efficacy of the gum in helping smokers to stop their cigarette habit and in successfully withdrawing from nicotine itself.

Side Effects and Adverse Reactions

The most common side effects are related either to the nicotine or to the gum dosage form. Nicotine effects can be local (oral irritation, 20% incidence) or systemic (nausea, 14%, hiccups, 11%, lightheadedness, 20%). The gum vehicle may produce local (trauma to loose teeth), mechanical (jaw muscle ache, 9%), or gastrointestinal effects (belching, 5%). These effects, with the exception of dental trauma and local initation can usually be managed by avoiding vigorous chewing.

Contraindications

Nicorette R should not be used by pregnant patients or by women who are breast feeding. Other contraindications include immediate post-MI patients, patients with severe cardiac arrhythmias, severe or worsening angina, and active temporo-mandibular joint disease (TMJ).

Toxicity on Overdose

Overdosage could occur if many pieces were chewed simultaneously or in rapid succession. It appears that risk of poisoning by swallowing the gum whole is small because release of nicotine in the absence of chewing is slow and incomplete. The patient may vomit spontaneously and systemic effects are possible. These include salivation, diarrhea, cold sweats, headache, dizziness, disturbed hearing and vision, mental confusion, and marked weakness. Hypotension may occur, and breathing may be difficult.

Treatment is the same as for acute nicotine poisoning. If there are no contraindications to emesis (drowsy, unconscious, absent gag reflex, seizures, caustics, antiemetics), give syrup of ipecac (consult the Poison Control Center at Farmington for assistance, 674-3456). Also, a saline cathartic given after the patient vomits will hasten elimination of gum. If ipecac cannot be used, perform gastric lavage with a large-bore tube, followed by activated charcoal.

Availability and Cost

Nicotine resin complex is available as Nicorette R from Merrell-Dow, in a chewing gum dosage form. Each piece contains 2 mg of the resin complex. A 4 mg strength is available in Canada but is not yet available in the United States. A box of 96 pieces will probably cost the client between $15-$20. It is estimated that the cost of using the gum will be no greater than the cost of cigarettes. Each piece of gum is packaged individually with its own identifying information. This minimizes the possibility of severe poisoning by children, while providing the benefits of unit-dose packaging.

Dosage and Administration

The average daily dose of Nicorette R is 10 pieces with a maximum of 30 pieces per day. Patients should be instructed to chew one piece of gum whenever they have the urge to smoke. Each piece should be chewed slowly and intermittently for about 30 minutes. This should result in an even, slow buccal absorption of nicotine. Fast chewing can release the nicotine too rapidly leading to effects similar to excessive smoking: nausea, hiccups, or throat irritation. Patients should be given a copy of chewing instructions provided by the manufacturer to help minimize these effects.

Gradual reduction in the use of the gum should be instituted if the patient has not spontaneously reduced gum use within six months. Use of the gum beyond six months is not recommended.

Summary

The availability of a nicotine-resin chewing gum now makes it possible for a smoker to work on the behavioral and social aspects of the habit while still receiving nicotine. It allows the smoker to begin to stop smoking in phases, rather than all at once. Both short-term and long-term studies demonstrated the efficacy of the gum and side effects have been minimal. My main concern with this product is not the efficacy, but the safety. As with all drugs, we never really know the extent of side effects until a drug has been used in general practice. Our premarketing optimism for Nicorette R should be guarded as we may see more frequent and more severe side effects than were indentified in the premarketing studies. The overdose potential is of particular concern. Nicotine is highly toxic (40-50 mg can be lethal) and potential serious poisoning is possible. Hopefully, the unit-dose packaging and limited release characteristics of the gum dosage form will prevent serious toxicity.

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Calcium Channel Blocking Agents

AMA COUNCIL ON SCIENTIFIC AFFAIRS

The Council on Scientific Affairs is charged with the task of advising the AMA's Board of Trustees "on substantial and promising developments in the scientific aspects of medicine and biomedical research that warrant public attention." Many innovations in diagnosis and drug usage are introduced every year and various award-giving bodies attempt to assess those that will be most important. However, it is difficult to know at what point the medical profession should be alerted to an important new advance, especially when commercial interests are involved. The natural enthusiasm for a novel approach, abetted by good salesmanship, can lead to excessive use of the new treatment which finds its rightful place in the therapeutic armamentarium only some years later, after being tempered by sober experience.

The category of drugs designated as slow calcium channel blocking agents is seeing quick and enthusiastic acceptance in cardiological practice since its initial approval by the Food and Drug Administration (FDA) in 1981. Not only have these drugs lived up to the early promises made by their sponsors, but their effectiveness in relieving symptoms is sufficiently impressive that both patients and physicians have been quick to accept them. Furthermore, the two initial indications for their use, as recognized by FDA-approved labeling, may be only the first of many. Not only is it reasonable to say that cardiological practices will see a permanent change because of these drugs, but other areas of medical practice will be affected as well.

The Calcium Channel

The calcium ion flux through cell membranes is important in the function of many tissues, including cardiac and smooth muscle. During the passage of the cardiac impulse, and following the initial phase of depolorization, calcium ions are transferred across the myocardial cell membrane through the activation of a slow inward channel. The initial fast change in membrane potential is accompanied by a sodium influx through a different "fast" channel. Thus, the slow calcium channel across the membrane is represented in the slower phase of the action potential and is thought to be important in excitation-contraction and excitation-secretion coupling.

That separate channels exist in the sarcolemma, each with a system of gates, for Na^+, K^+, Ca^{++} and perhaps other ions, is now well established. These channels' exact anatomic structure and mode of action require further elucidation. However, as knowledge of these ion exchanges increases, it is apparent that the rate of rise of the action potential, the duration of contraction, the rate of relaxation, the speed of recovery for reexcitation and the rate of conduction of the impulse are all more or less dependent upon the slow calcium channel action. In fact, the action of beta adrenergic agonists and of the digitalis glycosides are both in some measure dependent upon the calcium channel.

For at least 15 years, calcium channel (or calcium entry) blocker drugs have been in clinical use in Europe, although their mechanism of action is only currently being appreciated. Drugs that have been used have demonstrated different degrees of selectivity in their effects on vascular smooth muscle, myocardium or specialized conduction and pacemaker tissues which have important clinical implications. This fact has been well confirmed by the differences in chemical structure and pharmacologic activity of the three drugs that have been released for use here by the FDA: nifedipine, verapamil and diltiazem. Additional calcium antagonists are under study and it is anticipated that clinicians may eventually have drugs that will be more specific both as to basic action and as to specific organ affected.

By altering intracellular distribution or binding of calcium in cardiac and smooth muscle cells, these blocking agents dilate coronary and peripheral arterioles, alter heart rate, decrease myocardial contractility and slow A-V conduction. The electrophysiological and hemodynamic effects vary from one drug to another: according

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*This report is not intended to serve as a standard of medical care: standards of medical care which are determined locally and are constantly subject to change are established on the basis of the several factors of the individual case.

Action of the House of Delegates (1982 Interim Meeting): Report E of the Council on Scientific Affairs *adopted.*

to their selectivity of action on smooth or cardiac muscle or on pacemaker or conduction tissue cells, and depending upon their ancillary properties. Variation also results from the degree to which ventricular afterload reduction and reflex beta-adrenergic response counter their direct negative inotropic, chronotropic and dromotropic effects.

Indications For Use

Angina Pectoris

The only FDA approved therapeutic indication for nifedipine is angina pectoris. Verapamil was approved earlier for its antiarrhythmic properties and diltiazem has, like nifedipine, been approved more recently for use in both vasospastic and chronic stable angina pectoris. It has been demonstrated that coronary spasm can be abolished by acute administration of the drug, and classical Prinzmetal's variant angina is well controlled by requested administration of nifedipine or diltiazem. In addition, unstable angina, which often has a component of coronary spasm, has responded better to nifedipine than to nitroglycerin administration. Thus, angina at rest, which is presumed frequently to have an element of spasm, responds to the requested administration of the drug. Even angina of effort is favorably influenced by requested use of the drug, although carefully controlled studies suggest the effect may be no better than that seen with chronic use of long-acting nitrates or beta-blockers. Verapamil is as effective as nifedipine in this regard, but has less effect on the systemic circulation and a much greater depressant effect on S-A and A-V nodal tissue. Verapamil is less often a cause of reflex tachycardia and, in fact, may induce mild bradycardia in addition to carrying significant anti-arrhythmic properties. More double-bind randomized trials comparing one calcium channel blocker with another, with beta blockers, with and without accompanying nitrates are needed. Nevertheless, there is little doubt that these pharmacologic agents aid in the management of several types of angina pectoris, both by relieving coronary spasm and by reducing myocardial work.

When a calcium antagonist and a beta-blocker are used together, the fall in blood pressure may be dangerous. Perhaps more important is the fact that the negative inotropic effect that may precipitate heart failure and the enhancement of A-V heart block are additive when the two kinds of drug are combined. (There is some indication that nifedipine may have a weaker negative inotropic effect than the others.) Nevertheless, there have been instances where, under close monitoring, the combination was more effective in relieving angina than either one alone perhaps because the beta-blocker will offset the tachycardia induced by the former. A beta-blocker, when it is poorly tolerated or contraindicated, can often be supplanted by one of these calcium antagonists.

Antiarrhythmic Properties

The first calcium blocker to achieve FDA approval was IV verapamil for the treatment of paroxysmal supraventricular tachycardia. It was also found to slow the ventricular rate in atrial fibrillation and flutter. On the other hand, it does not affect the rate of retrograde conduction in the pre-excitation syndrome and deleterious effects have been seen when using it to treat some cases of atrial fibrillation with the pre-excitation syndrome. Diltiazem has anti-arrhythmic effects also but they are less than those of verapamil. Nifedipine has little or no anti-arrhythmic effect.

None of these agents is considered to be clinically effective in controlling acute or chronic ventricular ectopic rhythms. Yet, if the ventricular arrhythmia is a manifestation of myocardial ischemia, especially in variant angina, one of them may correct the ventricular ectopy. Verapamil should generally be avoided in the sick sinus syndrome, 2nd or 3rd degree A-V block, cardiogenic shock or congestive heart failure (unless, of course, the latter is secondary to ventricular tachycardia). At present neither verapamil nor diltiazem has been approved by the FDA for the oral prophylaxis of supraventricular tachyarrhythmia. Available data however, suggest, at least in the case of verapamil, that recurrences of paroxysmal supraventricular tachycarias are reduced in frequency and the ventricular response in atrial flutter or fibrillation, both at rest as well as with exercise, is attenuated. There is no evidence that these drugs reduce the relapse rate in patients converted to sinus rhythm by electrical conversion.

Other Cardiovascular Indications

There are several other indications for the use of calcium channel blocking agents, even though beta blocker or other categories of drugs may often serve as well. For example, there have been reports of successful treatment of the following conditions with these agents.

Animal experiments and some clinical experience have suggested that nifedipine may well improve regional flow to ischemic areas and reduce the zone of infarction during the early stages of an *acute myocardial infarction.* On the other hand, the reduction in blood pressure and coronary perfusion pressure and the potential negative inotropic effects on patients with severe myocardial impairment suggest that caution is required in this case. Properly controlled clinical studies will be necessary to determine the safety and efficacy of these agents for this indication.

Hypertrophic cardiomyopathy is now treated by beta-adrenergic blocking agents that control symptoms in many patients and may postpone, if not preclude, operative intervention. These calcium blocking agents in preliminary studies on patients with this condition have increased ventricular compliance and ventricular filling, reduced the gradient at the base of the left ventricle, improved the exercise capacity and reversed symptoms of angina with less frequent side-effects than are seen with beta-adrenergic blocking agents. However, the basic physiological effects of the drug may lead to particularly adverse effects in this condition. Thus, the drug should probably be contraindicated in hypertrophic cardiomyopathy with left ventricular obstruction and a high wedge pressure, paroxysmal nocturnal dyspnea or orthopnea, sick sinus syndrome or significant A-V junctional disease.

Essential hypertension is known to respond to beta blockade and it appears as though some calcium entry blockers may provide a similar hypotensive effect in chronic essential hypotension. There have also been early trials using sublingual nifedipine as a potential alternative to diazoxide or sodium nitroprusside in the management of hypertensive emergencies and as an afterload reducing agent in early cardiogenic shock. Whether this or some other calcium channel blocker may be a useful agent in the management of chronic essential hypertension will depend upon long-term clinical studies.

Both primary and secondary *pulmonary hypertension* have responded to nifedipine with a subsequent reduction in pulmonary vascular resistance and increased cardiac output. Responsiveness probably depends upon the extent to which smooth muscle vascular spasm in the pulmonary arterial bed is a contributing factor to the hypertension. Preliminary results suggest promise in the management of patients with chronic air flow obstruction and acute respiratory failure. So far, no comparison has been made between any calcium blocking agent and other vasodilators, such as hydralazine and diazoxide, that have also been used in pulmonary hypertension.

Non-cardiovascular Uses of Calcium Antagonists

Because of their effects on smooth muscle contraction, there are many other disordered organ systems that may be affected favorably by these agents. For example, both verapamil and nifedipine have been used successfully in managing certain types of asthma, particularly exercise-induced asthma. The bronchospasm and vascular spasm of asthma is reduced by the calcium channel blockers in contrast to the increase that may be seen with beta blockade. When administered topically by inhalation, they can prevent asthma after exercise in patients who have this symptom pattern. Verapamil does not necessarily counteract asthma triggered by histamine release, but at least these drugs can be used for other indications in patients who do have asthma or chronic obstructive lung disease.

Nifedipine has been shown to be effective in the esophageal motor disorders, achalasia and diffuse esophageal spasm. In clinical studies, significant reductions in lower esophageal sphincter pressure and frequency of spontaneous esophageal contractions and amplitude of distal peristaltic esophageal contractions have been accomplished by the use of nifedipine in some patients with achalasia. Gastric emptying is apparently not affected and reflux esophagitis may be aggravated, but painful esophageal spasm can be relieved by sublingual use of nifedipine. Isosorbide dinitrate will bring the same relief, but its side-effects are more troublesome.

There is some indication that verapamil and nifedipine may interfere with platelet function, although their possible role in the control of thromboembolic phenomena has not been studied.

The possible use of these drugs in cerebral vasospasm, intestinal ischemia, and in obstetrical problems still remains to be explored.

Side Effects

These drugs are, in general, well tolerated with few side-effects not anticipated from the pharmaco-dynamics. Most studies report the incidence of undesirable side-effects to be less than 10%. Nifedipine may lead to flushing, headache, tachycardia, hypotension, dysesthesia and fatigue; while for verapamil, constipation, headache, dizziness, hypotension, fatigue and A-V block are mentioned. Diltiazem adverse effects that occur in more than 1% of patients include nausea, edema, headache, rash and fatigue. All three can cause an edema that is not due to heart failure. The drugs are relatively contraindicated in the sick sinus syndrome, second or third degree A-V block, shock and congestive heart failure. Verapamil and nifedipine may increase serum levels of digoxin. Experience to date indicates that this effect is more pronounced with verapamil than nifedipine. Therefore, patients on digoxin run the risk of toxicity when taking these drugs and should be carefully monitored.

Commentary

Under the Federal Food, Drug and Cosmetic Act, a drug approved by the FDA, "may be labelled, promoted, and advertised by the manufacturer only for those uses for which the drug's safety and effectiveness have been established and which FDA has approved." While this means that adequate and well-controlled clinical trials have documented these uses, it does not preclude the use of that drug for other less well-documented indications. The FDA itself has noted:

> "Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabelled" uses may be appropriate and rational in certain circumstances and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature."[5]

From the above discussion, it can be seen that there is a wide spectrum of cardiovascular and other disorders that may also respond to these calcium channel blocking agents. This new category of drugs provides the promise of many variations upon the three that are already approved by the FDA. It will probably take years before the final role of each of these drugs, in the various indications that have been proposed, will be established.

Conclusion

The Council on Scientific Affairs advises the medical profession that a new class of drugs for the treatment of certain types of angina pectoris and supraventricular arrhythmias has been approved by the FDA.

The CSA also reiterates that it is appropriate and legal for physicians to prescribe approved drugs for uses not included in their official labelling when they can be supported as rational and accepted medical practice.

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DRG VALIDATION STATEMENT is offensive to many physicians, AMA Executive Vice President James H. Sammons, M.D., informed the Health Care Financing Administration. The certification statement, which physicians must sign for Medicare reimbursement under the prospective payment system for hospitals, is a "recitation of criminal and civil penalties" that could be imposed if the physician incorrectly identifies the diagnoses or the procedures for which HCFA is being billed, Dr. Sammons said in a letter to HCFA Administrator Carolyne K. Davis, Ph.D. Dr. Sammons asked Dr. Davis to consider withdrawing the statement, which he said was not mandated in the DRG law but, rather, was required by HCFA's final rule implementing the law. AMA representatives held an exploratory meeting with Dr. Davis and her staff April 19 in Washington, D.C. HCFA agreed to continue meeting with the Association for further discussions on the issue.

BIOETHICAL ISSUES continue to be the pre-eminent concern of the AMA Judicial Council, Chairman Samuel R. Sherman, M.D., told the executive committee of the AMA Board of Trustees. The council is developing an opinion on living wills and the question of whether a conscious, apparently competent patient who refuses needed treatment should be declared incompetent so that consent to treatment may be obtained. The council also will examine whether the withdrawal of nasogastrically or intravenously supplied food and water from a dying patient is morally distinguishable from the withdrawal of respirators and other life-support technology. The role of hospital ethics committees also will be considered. "The Judicial Council believes the AMA has a responsibility to assume a major role in the decision-making process in all of these issues," Dr. Sherman said.

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Month In Washington

Mandatory Assignment Defeated

In major action in April, the House rejected a plan that would have required physicians to accept assignment on all Medicare inpatient claims.

The legislators may move instead toward adoption of a Senate alternative, endorsed on April 14, which would freeze prevailing and customary fee limits for all physicians for one year. The freeze would be continued on prevailing fee limits for a second year for those physicians who refuse to take all claims on assignment.

The rejected House measure would have frozen Medicare fee limits on physician services to hospitalized patients and mandated assignment of all inpatient claims. Hospitals, as a condition of Medicare participation, would have been required to deny staff privileges to physicians refusing to sign commitments to accept all Medicare claims on assignment.

The measure was pushed by the House Democratic leadership with the support of the American Association of Retired Persons (AARP) and the National Council of Senior Citizens but was vigorously opposed by the American Medical Association and other physician groups. Its defeat was seen as a victory for physician lobbies.

The matter will now be taken up in a conference with the Senate which included its physician freeze and assignment changes in a Finance Committee package of spending and tax measures approved in a marathon Senate session just before recess.

The Senate specifically stipulated that Sens. Edward Kennedy (D-MA) and Max Baucus (D-MT) may offer amendments to the Medicare section. Kennedy intends to offer amendments that would eliminate increases in the Part B deductible and premiums called for in the Finance bill. Baucus also wants to eliminate the increase in the Part B deductible but would allow the premium increase to remain in effect through 1986 and then sunset in 1987. Both may offer language to add a monitoring mechanism to the physician freeze proposal.

Prepared by the Washington, D.C.
Office of the American Medical Association

No-fault Malpractice Bill Introduced

A professional liability bill that was more than a year in the making has been introduced in Congress by Reps. Henson Moore (R-LA) and Richard Gephardt (D-MO).

Called the Alternative Medical Liability Act (H.R. 5400), the measure would apply a no-fault approach of sorts to patients whose care is paid for by the federal government. These would include Medicare and Medicaid beneficiaries as well as military personnel, veterans and federal employees, the sponsors say.

The bill would limit the patient's claim to malpractice awards if the hospital and/or physician offered a settlement within six months of the occurrence on which the claim is based.

The settlement would be based solely on the patient's economic loss—including wage loss, and the cost of rehabilitation and medical treatment. Once the offer had been made, the patient would have no further recourse through the courts except to dispute the appropriateness of the amount. He could not sue for pain and suffering or other damages.

In cases where the provider did not offer a settlement, the current tort system would continue to apply. Unlike an earlier draft, the latest measure leaves the burden of proof with the plaintiff.

The bill also gives states the option of setting up their own malpractice insurance systems that meet the above criteria. In states that hadn't acted by January 1, 1987, the federal law would take effect. Gephardt and Moore say they hope that some states will go beyond the federal law and apply its criteria to all state residents—not just those who are federal beneficiaries.

* * * *

Downturn in Rising Hospital Costs Reported

Hospitals and federal agencies have reported a downtrend in rising hospital costs that some observers are attributing in part to the implementation of Medicare's diagnosis related groups.

Data detailing the new trend was presented to the Congressional Joint Economic Committee by American Hospital Association Executive Vice President Jack Owen who said the statistics show that DRGs are working and that they are holding down costs for other payers as well as for Medicare.

In 1983, the rate of increase in total hospital expenses slowed from 15.8% in 1982 to 10.2% in 1983. The reduction in the rate of increase in inpatient expenses was even greater—from 15.6% in 1982 to 9.6% in 1983.

Owen said the lower rates of increase are due in part to a slowdown in hospital hiring rates and to a drop in utilization of hospital services. Hospital exployment rose by only 1.4% in 1983, he reported, compared to 3.7% in 1982. Overall admissions decreased by 0.5% in 1983 and even admissions for those 65 and older, which went up by 4.7%, did not increase as rapidly as in previous years. Lengths of stay for patients 65 and older were down by 4.5%.

* * * *

Costs Up, but Americans Living Longer, Better

By 1983, health care costs in the United States were more than $350 billion—up 770% from 1965. In 1984, for the first time, Americans will spend more than $1 billion a day on health care.

During similar periods of time, however, American life's expectancy has increased by about five years and infant mortality rates have been halved. Deaths from heart disease have declined by 25% and deaths from stroke by 40%. The advances have come about through major technological improvements which themselves often are costly and which increase costs still further by keeping more people alive longer.

These two sides of the health care cost argument were presented before a Joint Economic Committee hearing April 12 in a hearing that in some respects pitted the nation's large corporations against health care providers.

Most outspoken among the corporate representatives was former Department of Health, Education and Welfare Secretary Joseph Califano, a Washington lawyer who now heads a special Chrysler Corporation committee on health care. Califano told the congressional committee that health care costs are "an unfair burden . . . for American business as it seeks to compete with foreign industry." He reported that in 1984, Chrysler will have to sell about 70,000 vehicles just to pay its health care bills of more than $400 million or about $5,700 per active employee. He contrasted that with the $815 a year the Japanese Mitsubishi Motor Corporation (in which Chrysler has an investment) spends per worker.

Califano and other business representatives, including Ford Motor official Jack Shelton, complained that government efforts to hold down health costs to date have shifted costs to business. Between 1970 and 1982, Shelton said, health costs in the United States rose by 332%. At the same time, business health care costs went up by 700%.

An American Association of Retired Persons (AARP) representative said costs are also being shifted to the elderly through some $26 billion in Medicare cuts in the past three fiscal years.

But American Hospital Association Executive Vice President Jack Owen reported that Medicare is not currently shifting costs. He said, however, that shifts may occur if prices for diagnosis-related groups are lowered appreciably and observed that Medicaid is not paying its full share of costs.

Owen and AMA Board Member Alan Nelson, M.D., also maintained that health care costs are due for the most part to improved technology and better access that came about as a result of consumer demand. Even, if one assumes that all waste in the health system could be rooted out entirely, Dr. Nelson said, "the cost of health care probably would show a one-time drop and then resume its climb unless technological advances are halted. As long as technological capabilities improve and as we continue to live longer, then of course costs will go up," he told the committee.

* * * *

Senator Says Competition is Working

Amidst predictions that the Medicare hospital trust fund will be depleted by 1991 or shortly thereafter, one influential U.S. Senator is arguing that Congressional action to fix Medicare now would be premature.

Sen. David Durenberger (R-MN), a champion of the competition approach to holding down health costs, said at a recent Senate Finance Committee hearing that he believes today's solutions to the Medicare problem may not be needed or applicable by the projected date of bankruptcy. His arguments are based on the premise that competition is already taking hold in the health field.

The hearing concentrated on the recommendations of a Medicare advisory group chaired by former Indiana Gov. Otis Bowen, M.D., but also focused on projections regarding the actual date at which the hospital fund will be depleted.

* * * *

FTC Pokes Into Physician Ads

At an April meeting sponsored by the Federal Trade Commission, participants debated the advantages and disadvantages of "quality claims" in professional advertising.

Traditionally, medical ads have described only the physician's office hours, specialty, address, and phone number. Now, an increasing number of ads describe the physician's qualifications as well.

"I predict a transition from advertising 'kind of practice' to 'quality of practice' which will trigger a whole new round of (legal) fights," says attorney Nancy Buc of Weil, Gotshal & Manges.

Physicians, for the most part, said they fear that patients are easily led astray by exaggerated claims of competence. John Munna, M.D., of the American Society of Plastic and Reconstructive Surgeons said the ads "offer unrealistic psychological inducements."

Said Robert Moser, M.D., of the American College of Physicians: "The sole purpose of advertising is to persuade a consumer to purchase a product. When slick Madison Avenue techniques, designed to appeal to the emotions, are applied to the health care, the consumer could be influenced to make a dangerous and bad decision."

According to FTC staffers and attorneys, however, the medical profession's fears are exaggerated and unjustified. The FTC has received many complaints on health care advertising from professionals. Upon investigation, however, most of these ads were neither false nor deceptive, but simply demeaning to the profession, according to FTC attorney Jonathan Bromberg.

There is little evidence of fraudulent or misleading advertising, according to Irwin Braun, President of Braun Advertising, Inc. Of five state regulatory agencies contacted by Braun, few reported any incidents of problem advertising. One state attorney told him: "The majority of complaints are from other professionals. We have practically no consumer complaints." Even when ads do violate the law, it is the professionals, not consumers, who notice, Braun says.

The FTC has no precise definition of what exactly constitutes a "false and deceptive" quality claim. It looks for evidence of actual harm, either physical or monetary; an ad that is simply distasteful receives little FTC attention. In the past several years, they have prosecuted roughly a dozen cases.

The FTC language regarding advertising is so broad that it appears to render the medical community powerless against an unethical physician advertising his services," AMA President-Elect Joseph F. Boyle, M.D. said.

Professional societies are reluctant to jump into the fray, fearing anti-trust litigation. Most medical societies still monitor local advertising: first-time offenders are reprimanded and repeat offenders may be suspended or dismissed from the society. The AMA has a policy against false and deceptive advertising. But the old code of ethics against advertising is no longer.

Participants in the meeting urged the AMA and FTC to work together to combat deceptive ads. They could design a brochure that would define legitimate advertising to AMA members. But, the FTC should confine their vigilance to overseeing physicians' enforcement of their own rules, leaving them free of direct regulation, they proposed.

The FTC offered an olive branch: "We're not opposed to self-regulation to professionals as long as it is intended to reduce deception, not preserve self-interest," said Michael McCarey of the Bureau of Consumer Protection. "The AMA has a valuable and unique role to play here."

"We ask that if you see an example of deception, please send us a copy, explaining why it is deceptive, with substantiation, if possible," he said.

* * * *

Ophthalmologists Call on FTC

The American Academy of Ophthalmology asked the Federal Trade Commission (FTC) in April to investigate "false and misleading" advertising by optometrists, saying the ads pose a serious threat to consumers.

Before taking action, however, the FTC says it may need evidence that the ads actually harm patients and are not simply part of an ongoing jurisdictional battle between the two professions.

Information in the ads that can mislead the public, according to the Academy, includes:

- References to "Dr. Jones, diseases of the eye," or to services such as cataract surgery which optometrists cannot perform legally.
- Use of the phrases "optometric medicine, medical optometrists, optometric physicians, or eye doctors in family practice."
- References to "total eye care" or "complete eye care services."
- Misleading definitions of ophthalmologists and optometrists.

The Academy does not wish to single out individual advertisers, but wants the FTC to investigate the general tone of optometric advertising, according to Academy attorney Clifford S. Stromberg.

The FTC will first determine whether the problem is confined to "fringe" practitioners or is industry-wide. If it decides there is evidence of a general dispute, it will then look for measurable harm—either physical or monetary—to consumers. This may require an extensive study of public perception of the differences between the two professions.

* * * *

AIDS Virus Found

The big news in science from Washington in April was the report from Cancer Institute scientists that they had most likely found the cause of AIDS. Sensitive to charges that the AIDS problem was not getting all the attention it should, Department of Health and Human Services pulled out all the stops and held a high level press conference by Secretary Heckler to announce the finding. Scientists say the cause is most likely a virus that attacks the cells of the body's immune system.

AMA Calls for Pro Changes

The American Medical Association has requested modifications in the federal government's proposed method of contracting for oversight by peer review organizations (PROs) of hospital care to Medicare patients.

In a letter to Health Care Financing Administration head Carolyne Davis, Ph.D., the AMA called for added flexibility in the fixed price contracts the government will sign with PROs. The Association also urged that pre-adminission review requirements detailed in a request for PRO contract bids be modified and called for an extension of the April 27 deadline for submitting PRO bids.

Meanwhile, proposed regulations governing the confidentiality of data collected by Medicare peer review organizations (PROs) and the use of PRO-recommended sanctions were issued late in April by the Health Care Financing Administration—just weeks before final PRO bids are due.

Final rules weren't issues until after the April 27 deadline for bids from organizations competing for PRO contracts, however, leaving open the possibility that the PRO contracts will have to be amended if changes are made in the final rules as a result of comments on the proposed regulations.

* * * *

More on Assignment

A new bill from Sen. John Heinz (R-PA) would set up Medicare physician fee schedules and require physicians to accept assignment on all claims for services to Medicare inpatients.

The bill provides financial incentives for states to develop health care cost containment plans pertaining to all third party payers. To be called the Medicare Incentives Reform Act, the bill would also limit out-of-pocket costs for Medicare beneficiaries and increase federal excise taxes on cigarettes.

* * * *

Physicians Protesting Medicare Statement

Groups representing organized medicine have asked the Health Care Finance Administration to either modify or withdraw a new statement they are being required to sign as part of Medicare's new diagnosis related groups payment system.

The statement, which must appear within the medical record of discharged hospital patients, requires the physician to attest that the principal and secondary diagnosis and procedures listed in the record are accurate. It also warns that intentional misrepresentation or fraud in connection with the record is "punishable by imprisonment, fine or civil penalty."

In a letter to Health Care Financing Administration head Carolyne Davis, Ph.D., the American Medical Association observed that there "is no mandate in the DRG law for the certification form" and requested a meeting to "explore whether this regulation can be withdrawn."

* * * *

Doctors on Standby

A controversial plan to register both female and male physicians in a peacetime draft was quietly set aside in April by the Pentagon.

Instead, the "doctor draft" has been included in a large "mobilization day" contingency plan, to be implemented only in the event of war.

The now-defunct proposal, if enacted by Congress would have made women eligible for the draft for the first time in American history. The plan was to amend the Selective Service Act by striking out the term "male" health professional and substituting the term "person." Among the "persons" described: female physicians, nurses, physical therapists, pharmacists, podiatrists, veterinarians, and "any other ancillary or technical health care worker between the ages of 18 and 46 years old."

Facing strong opposition by the American Nurses Association and other groups, the new proposal includes a plan to draft women health care professionals and does not need peacetime congressional approval. Instead, it will be part of a plan that will be handed over to Congress within a day or two of "World War III or another national emergency," according to Pentagon spokesmen.

* * * *

Dr. Custis Resigns VA

One of the most powerful men in American medicine, Donald L. Custis, M.D., Chief Medical Director of the Veterans Administration, resigned from his post this month.

The 67-year-old surgeon, began his military career as a staffer at the U.S. Naval Hospital in Portsmouth, VA, then going on to become medical officer on an attack transport in WW II, chief of surgery at the Naval Hospital in Cuba, and commanding officer of the Danang Naval Hospital in Vietnam.

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Editorial

Informed Consent: A Changing Standard of Disclosure

Although lack of informed consent is frequently an allegation in malpractice suits, rarely in our state has a case turned solely upon this issue, previously judged by "customary *medical* practice in the community." The Editor of *Connecticut Medicine* has seen fit in this issue to publish the Connecticut Supreme Court decision in the appeal of the recent *Logan v. Greenwich Hospital Association et al.* case. As Chairman of the Society's Committee on Professional Liability, I concur with the Editor that this decision should be recommended reading for the practicing physicians of our state, because it represents an evolution of the standard for informed consent in the courts of our state, a standard by which physicians will be judged in future medical negligence actions.

Up until now, a physician might have assumed that he or she was not obligated to disclose to a patient alternative procedures considered to be more hazardous than the one recommended. This is no longer the case, because under *Logan,* the *professional* "doctor knows best" standard of disclosure has been replaced by the *lay* standard, which requires disclosure of such information as a "reasonable patient would consider *material* to the decision whether or not to undergo treatment or diagnosis, "the implication being that a patient has the right to choose among varying risks and benefits. In the *Logan* case, a maloccurence occurred during the procedure deemed less hazardous, a needle biopsy of the kidney, and the Supreme Court remanded the case for a new trial on the issue of informed consent, because "the trial court *erred* in instructing the jury that a physician, in obtaining a patient's informed consent, need not discuss with him any alternative which is more hazardous than the treatment the physician has recommended."

In its instruction to the jury, the trial court had also stated that "an alternative that is more hazardous is not a viable alternative." Such a jury instruction would, the Supreme Court said, relieve the physician "of any obligation to discuss alternatives, and substitutes merely a duty to recommend the safest procedure." In the appeal, the plaintiff had taken exception to this instruction, and the Supreme Court agreed that the instruction was incompatible with the view that "the patient must be provided with sufficient information to allow him to make an intelligent choice."

While the *Logan* case expands a physician's duty of disclosure to a wider range of information considered "material" to a patient's decision, including the risks and benefits of procedures deemed more hazardous, it might also lessen a physician's responsibility concerning disclosed risks encountered, in the absence of negligence. However, only further development of case-law will reveal the distribution of responsibility between the patient and physician under the new standard. Meanwhile, a careful reading of the *Logan* decision will provide physicians with vital and current continuing medico-legal education concerning the elements and importance of informed consent under the lay standard of disclosure. Such "CME" can save us much grief in the future.

Mehdi Eslami, M.D., Chairman
CSMS Committee on Professional Liability

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1974-Present—Member of Council, Connecticut State Medical Society
1977-1979—Chairman of Council, Staff Council, St. Francis Hospital & Medical Center, Connecticut Representative
1978-Present—Joint Socioeconomic Committee of American Association of Neurological Surgeons, Congress of Neurological Surgeons
1978-Present—Connecticut Representative Council of State Neurosurgical Societies

The President's Page

Maybe the Time Has Come

It is with some trepidation that I enter this coming year as president of CSMS. It is a time when physicians, their patterns of practice, incomes and life styles are increasingly coming under attack from many areas, including government, third party payors and all types of "providers" who are attempting to breach the domain once exclusively reserved for the physician. I sincerely hope I have the ability and perseverence to cope with this onslaught.

During my 15 years of involvement in medical politics, I have been impressed by the interest or lack of same demonstrated by physicians regarding problems, real or imagined, which affect doctors and their patients. As a general rule, physicians are novices when confronted with the political process or legal maneuverings. Because of this we react to the problems which arise rather than formulating long term goals and striving for them.

Our ultimate long term goal should remain, as always, the provision of the best medical care for our patients at a reasonable cost. Adequate personal recompense will follow from this.

There are many ways to pursue our goals and I would like to address one of these now, namely, physician involvement. I am reminded of the time when, as an officer of my County Medical Association, I was approached by another physician in the hospital while making rounds, who stated that he had received some mail from the County Association, didn't have time to read it, and wanted me to explain to him the contents of the information sent to him. This is not involvement.

As one who speaks with patients regarding their jobs and at time about their political leanings, I have been impressed by the involvement of many unionists in the aims of their unions as enunciated by their leaders, both with personal involvement which requires the expenditure of their free time and also with the giving of their hard earned money. I've been lead to believe that a member of the Teamsters Union contributes more money to his organization than the average doctor does to all professional organizations to which he belongs. Yet, both the unions and organized medicine are both equally concerned with the welfare of their members.

One area which has concerned me for a long time is the lack of a grass roots organization to affect the political process which at times passes laws having a great impact on ourselves as well as our patients, with minimal or no physician input into the legislative process. Recent activities of Connecticut's legislature will attest to this fact. It is extremely difficult to understand how this situation could come to pass in a society where only a few years ago, such a move would never even be contemplated. Individually physicians are respected but collectively we're considered patsies.

Maybe the time has come for physicians to become truly organized and not just reactionary. An easy beginning can be made from which significant grass roots physician involvement in the legislative process can grow. There is no doubt that all legislators have either personal physicians or include doctors among their social or business friends. If these physicians would volunteer their services to the State Medical Society along with the legislators with whom they have contact, an organization can be built which could be a potent force in putting forth our views as well as those of our patients, and in so doing, serve a tremendous educational effort in propounding our point of view to the lawmakers.

The time for involvement is now, not 1986. Kindly contact your county and state societies and volunteer your time and effort in this manner. Don't wait for your officers to do it for you. They don't know everyone and also have practices to maintain. It's a fact, besides money, personal contact with legislators is extremely effective, as was demonstrated in the recent defeat of the Rostenkowski Amendment in Congress. *Maybe the time has come* for action rather than reaction.

Joseph S. Sadowski, M.D.
President

Reflections from the Dean's Office

Story Telling and Technology Transfer

ROBERT U. MASSEY, M.D.

Technology transfer is by no means a new notion, but the words are heard more and more as both scientists and businessmen seek ways to move the discoveries of basic research into the marketplace, biomedical research to the hospital and clinic. The plentiful supply of investment capital and the outpouring of new information from the world's scientific laboratories have come together to make technology transfer itself a profitable business.

The concept applies as well to scholarly work other than basic scientific research: history, for example, and the history of science and medicine, or medical sociology and medical economics. Just as biochemists report their serious work in journals intended only for other biochemists, so historians or economists may write only for other historians and economists, sometimes more attracted to the methods of scholarship than to its object, employing words and making allusions familiar only to the inner circle. More perhaps than the biochemists and others working in the natural sciences, historians and social scientists may fall into one or another of the currently fashionable ways of interpreting history, and, like some modern journalists, mix findings with social theory, facts with editorial comment.

History may be used to support almost any social doctrine, political ideology, economic theory, religion, professional point of view, or patriotic impulse. So can biology or physics. It depends upon who is telling the story in the case of history, or who is transferring the technology in the case of science.

As early as the sixth century B.C., the merchants and sailors in the busy Ionian city of Miletus suffered and apparently supported philosophers in their midst, valuing them for the contribution which they could make to an understanding of the world. The pre-Socratic philosophers, Thales, Anaximander, and Anaximines, were perhaps the first ever to suggest rational rather than mythical explanations for natural phenomena; they also helped to solve practical problems of navigation and commerce by using their knowledge of astronomy, geometry, and geography. Here was a kind of technology transfer, and, although many details of their world are missing, we may suppose that they were honored for the philosophy and were supported because of their useful contributions, and maybe even because they "made it all so interesting."

The best history, even the best natural history, is good literature; in ancient times it was often told as poetry. Historical scholarship has developed mostly in recent times as a way to check up on the old stories. Western science may have started, back on the coast of Asia Minor in Miletus, for similar reasons: as a way to check up on the old myths.

But to complete the cycle, maybe to fulfill a contract, the old stories and the old myths have to be retold in the light of the new scholarship or the new research; either as story or as art they have to be returned refurbished to the community, because it is after all the community, especially in a democracy, to whom the scholars and scientists must look for their continued sufferance and support.

The first steps of the transfer are made by the scientists and scholars themselves when they leave their laboratories or their libraries for the classroom; it is when they stop talking to one another and begin to explain to students, turning their laboratory data and notes into a story, that even they may first come to understand the significance, or the lack of it, of the work they have been doing. Transferring, storytelling, making useful are not merely ways to prepare creative work for the classroom or the marketplace; they are, instead, ways to finish the job. Support for scientific research, or for the humanities, will be forthcoming only so long as the work is returned to society, only so long as there is a technology transfer. It is the task of the scientist and scholar to see to it that that is done with the same artistry as the work and as its fitting complement.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

in Brief

A summary of AMA, medical & health news

Computerized information services have been developed by the AMA in conjunction with the Centers for Disease Control and the Food and Drug Administration.The CDC uses MED/MAIL, the electronic messaging service of the GTE Telenet Medical *Information* Network to transmit alerts from its *Morbidity and Mortality Weekly Report* and to list training courses it offers to physicians and other health professionals. A third service, "CDC Info Update," monitors recent developments in the treatment of diseases. The AMA and the FDA have developed an electronic version of Form 1639, which physicians use to report adverse drug reactions experienced by their patients.

The Federal Trade Commission said it is closing an investigation of the AMA operating criteria for freestanding emergency centers. The guidelines were developed by the Commission on Emergency Medical Services. The American Assn. of Freestanding Emergency Centers had petitioned the FTC to initiate the investigation, charging that the AMA was restraining the ability of such centers to compete with hospital emergency rooms. The FTC found no basis to file a complaint against the AMA. It asked both the AMA and the AAFEC for assistance in a study of the centers' use of such terms as "emergency" and "urgent care."

Medicare assignment directories now being issued by the Health Care Financing Administration have a number of problems that should be reviewed and corrected in future editions, the AMA said in a letter to the HCFA administrator. The AMA recommended that the directory clearly state that assignment decisions are individual ones made between physicians and patients, and that both parties still need to discuss whether assignment will be accepted on any individual claim. "Failure to place such a caveat within the listing will only create greater confusion down the road if beneficiaries assume that a physician with a high percentage of claims accepted on an assigned basis will automatically accept their claim on such a basis," said the AMA.

Lifetime Cable Network will broadcast a TV series to be coproduced by the AMA. The series, titled, "Medicine Today," will contain clinical, social, and economic news drawn from AMA publications. The new venture, scheduled to start this fall, will supplement the previously announced cablecast of the AMA Video Clinic series. Lifetime is devoting 20 hours a week for medical programming targeted to physicians. For more information, contact Robert L. Bonin, AMA Headquarters, or phone 312-645-4596.

Ground was broken for EcuMed, a $2 billion medical education complex in Fort Lauderdale, Fla. The purpose of the international center, which will open its doors in 1987, is to keep physicians and other health professionals informed on clinical developments, products, and technology. EcuMed is expected to attract 600,000 visitors a year—120,000 from outside the U.S. It will have meeting facilities for groups up to 2,000. AMA Executive Vice President James H. Sammons, MD, is a member of the EcuMed board.

No-cost or low-cost care was provided by 76.8% of physicians in 1982, according to the Socioeconomic Monitoring System of the AMA Center for Health Policy Research. Providing free or reduced-fee care resulted in a 9.1% average reduction of potential revenues. Another form of uncompensated care is represented by unpaid bills. On average, 21.2% of physicians' total practice billings in 1982 were at least 30 days past due, excluding late payments from third-party payors. In addition, 6.3% of total practice billings in 1982 never were collected.

Physicians' income declined 3.0% in the six-month period ending in September 1983, compared with the same period in 1982. The decline was the first reduction in average quarterly net income recorded by the Socioeconomic Monitoring System since the program began in 1981. All major specialty groups experienced a decrease, although surgical specialties reported only a minimal loss. The AMA cautioned that the survey program had not accumulated enough evidence to determine whether the decline was the beginning of a trend or merely a transitory phenomenon.

Abortion 1983: The Controversy Continues: II

JOSEPH M. HEALEY, J.D.

In the recent case of *City of Akron v. Akron Center for Reproductive Health,*[1] the United States Supreme Court reaffirmed its commitment to the principles and regulatory framework governing abortion developed in the landmark 1973 cases of *Roe v. Wade* and *Doe v. Bolton.* Despite a strong dissent by Justices O'Connor, White and Rehnquist the Court affirmed its earlier decisions, clearly continuing to hold that there exists a constitutional right to privacy which includes the right of a woman and her physician to terminate a pregnancy by abortion. This right is not an absolute right and its exercise may be outweighed by the existence of a compelling state interest. Two such state interests have been identified. The first involves the state's interest in protecting maternal health and safety. The second involves the state's interest in protecting potential human life. To determine when one of these interests is sufficiently compelling, the Court in 1973 developed a framework based on the unfolding stages of the pregnancy. This framework, sometimes called the "trimester trilogy," applied the state interests at stages of the pregnancy to determine when they become compelling. Maternal health and safety becomes a compelling state interest at the point at which performance of the abortion involves significant health risks for the mother. At this point, the state may reasonably regulate the performance of abortion in the name of maternal health and safety. The second interest, protection of the potential life of the fetus, has resulted in confusion about when the state may prohibit abortion.

Connecticut is one of those states whose law shows the effect of this confusion and this month we will look at this issue in light of the *Akron* case.

Many Connecticut citizens are suprised to discover that there is a substantial body of law regulating abortion. Most of it is contained in regulations found in the *Public Health Code.* Among the areas covered are: who may perform abortions and where they may be performed, the various record keeping and reporting required, and a conscience clause protecting the rights of health providers to refuse to participate in abortions. The final section deals with one aspect of the "trimester trilogy":

> "(h) During the third trimester of pregnancy, abortions may be performed only when necessary to preserve the life or health of the expectant mother."[2]

Confusion arises because of the use of the term "third trimester." In its original decisions, the Court emphasized that the state's interest in regulating, even prohibiting abortion becomes compelling at that point in the pregnancy when the fetus has the capacity for existence independent of the woman. This point may occur at that point of time around the end of the second trimester and the beginning of the third trimester but its determination is not simply a matter of achieving a chronological milestone. Rather it is the recognition that the fetus has achieved a stage of growth and maturity enabling it to survive. Viability is a difficult concept to determine. Some commentators have assumed that the period of time subsequent to viability is automatically and invariably coterminous with the third trimester and this is clearly not true. A state law prohibiting abortion during the third trimester rather than during the period of time subsequent to viability is at variance with the Supreme Court cases culminating in the *Akron* case, and is unlikely to survive constitutional challenge.

One interesting implication of this distinction between third trimester and period subsequent to viability is the impact of technological progress permitting fetal maturity and fetal viability at earlier and earlier stages of the pregnancy. As such progress occurs, the state's ability to regulate and to proscribe abortion is likely to expand to cover an earlier period of the pregnancy. Technological innovation may be the source of further limitation on the woman's right to abortion.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

REFERENCES

1. 51 L.W. 4767, 1983.
2. The Public Health Code, Section 19-13-D54(h).

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The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

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MISCELLANEOUS

HOSPICE PHYSICIAN. Position available after June 1, 1984, to be part of the medical staff of the nation's first hospice. The Connecticut Hospice is a JCAH accredited hospital with a 44 bed inpatient facility and a hospice based home care program of 50 patients. Excellent opportunity for a physician interested in palliative care. Connecticut license required. Board Certification preferred. Full-time position but part-time applicants may be considered. Please send C.V. to John M. Stober, Director of Human Resources. The Connecticut Hospice, Inc., 61 Burban Drive, Branford, CT 06405. An equal opportunity employer.

CONNECTICUT MEDICAL DIRECTOR—MEDICAID. The State of Connecticut Department of Income Maintenance seeks a physician to advise on the Medical aspects of policies, standards and procedures of the Medicaid Program and administer the Medical Services of the Department. Qualified Candidates must have completed a residency in an AMA-approved hospital and five years employment as a member of the medical staff of an institution offering generalized Medical care or as a practicing physician. Salary range: $48,299-55,966/yr. Please send resumes to: Donna Dickson, Agency Personnel Administrator, Department of Income Maintenance, 110 Bartholomew Ave., Hartford, CT 06106.

OBSTETRICS/GYNECOLOGY

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OBSTETRICS/GYNECOLOGY—Continued

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A private medical practice in the town of Easton, CT is presently for sale. Suitable candidates would be either a general internist or family practitioner. Inquiries should be made to: Pasquale E. Perillie, M.D., Chairman, Department of Medicine, Bridgeport Hospital, 267 Grant Street, Bridgeport, Ct. 06602 (203) 384-3470.

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INTERNAL MEDICINE

HEMATOLOGY/MEDICAL ONCOLOGY. July '85. Age 31. Nat'l bds. AB cert. MD, State University of NY—Downstate Medical Center College of Medicine; Int. and Res., St. Vincent's Hospital and Medical Center, NY; Fellowship, University of Rochester Medical Center, Strong Memorial Hospital, NY. Prefers solo, group, associate or institutional type practice in a medium to large-sized community. Would consider full-time hospital based practice. Write, Denis Fitzgerald, M.D., 80 Cimarron Drive, Rochester, NY 14620.

NEPHROLOGY. Aug. '84. Age 33. Nat'l bds. AB cert. MD, NY University; Int., L.A. County—U.S.C. Medical Center; Res. and Fellowship, Kaiser Foundation Hospital, Los Angeles, CA. Prefers group or institutional type practice within several hours of greater New York area. Write, Richard B. Schwarz, M.D., 8300 DeLongpre Ave., #204, Los Angeles, CA 90069.

NEUROLOGY

Jan. '85. Age 30. Nat'l bds. AB cert. (IM); elig. (NEUR.). MD, Temple University; Philadelphia, PA; Int. and Res., Duke University Medical Center, Durham, NC. Prefers solo or group type practice. Write, Daniel Howley, M.D., 1819 Forest Rd., Durham, NC 27705.

ORTHOPEDICS

July '84. Age 30. Nat'l bds. AB elig. MD, New York Medical College, Valhall, NY; Int. and Res., Montefiore Hospital and Medical Center, Bronx, NY. Prefers group type practice in a medium to large-sized community. Write, Keith Kurland, M.D., 5900 Arlington Ave., Riverdale, NY 10471.

ORTHOPEDIC SURGERY

Aug. '84. Age 32. FLEX. AB elig. MD, Baroda Medical College, India; Int. and Res., Catholic Medical Center of Brooklyn and Queens, Jamaica, NY. Prefers solo practice in a small to medium-sized community. Write, S.N. Saraiya, M.D., 88-25A, 153rd St., #4F, Jamaica, NY 11432.

PATHOLOGY

July '84. Age 33. Presently in practice. FLEX. AB cert. MD, University of Tennessee, Memphis, TN; Res., Baptist Memorial Hospital, Memphis. Prefers solo, group or associate type practice. Write, Carlton L. Wallis, Jr., M.D., 26 Hillmont Cove, Jackson, TN 38305.

PEDIATRICS

July '84. Age 31. FLEX. AB elig. MD, and Int., Calicut Medical College, India; Res., Misericordia Hospital, Bronx, NY; Fellowship, University of Medicine and Dentistry of New Jersey (NEONATOLOGY). Prefers solo, group, associate or institutional type practice. Write, Kusumam Sidharthan, M.D., 222 Yorkshire Court, Old Bridge, NJ 08857.

PEDIATRICS—Continued

July '84. Age 31. FLEX. M.B.B.S. and Int., University of Jabalpur, Medical College, Jabalpur, M.P., India; Res., Victoria Hospital, Jabalpur, M.P., India, Clara Swain Hospital, Bareilly, U.P., India and Illinois Masonic Medical Center, Chicago, IL. Prefers group or associate type practice. Write, Satish Kumar Shrivastava, M.D., 856 West Nelson, Apt. #1506, Chicago, IL 60657.

PSYCHIATRY

Jan. '84. Age 61. Licensed in Connecticut. Nat'l bds. AB elig. MD, McGill University, Montreal; Int., Royal Victoria Hospital, Montreal; Res., Allan Memorial Institute, Montreal and Boston State Hospital, Boston; Fellowship, Worcester Youth Guidance Center and Alcohol Addiction, Massachusetts General Hospital, Boston, MA. Wishes institutional type practice and would consider research position (Pathology). Write, CSMS, JEM/PSY.

RADIOLOGY

DIAGNOSTIC. Aug. '84. Age 43. Presently in practice. Nat'l bds. AB cert. MD, Hannemann Medical University, Philadelphia, PA; Int., Roosevelt Hospital, NY; Res., NYU-Bellevue Medical Center, NY; Fellowship, Brigham and Women's Hospital, Harvard Medical School, Boston, MA. Prefers group, assoc. or institutional type practice in a medium to large-sized community. Has had nine years of general radiology including angio, nuclear medicine and ultrasound. Write, Eugene S. Barasch, M.D., P.O. Box 58, Harvard, MA., 01451.

SURGERY

VASCULAR. July '84. Age 31. Nat'l bds. AB elig. MD, Mt. Sinai School of Medicine, NY; Int., Res., and Fellowship, Mt. Sinai Hospital, NY. Prefers group or associate type practice. Write, Charles M. Miller, M.D., 1763 Second Ave., Apt. 21L, New York, NY 10128.

SURGICAL ONCOLOGY. Summer '84. Presently in practice. Age 35. FLEX. AB cert. MD, Christian Medical College (University of Madras, Vellore, India); Int., New Jersey College of Medicine and Dentistry, Neward, NJ; Res., Creighton University, Omaha, NB; Fellowship, Ellis Fischel State Cancer Hospital, Columbia, MO. Prefers solo, group or associate type practice in a medium to large-sized community. Write, CSMS, RVP/SUR.

June '84. Age 51. Presently in practice. Nat'l bds. AB cert. MD, Jefferson Medical College; Int., Williamsport General Hospital; Res., University of Miami and the University of NY at Buffalo. Prefers solo practice. Would like freedom to do a wide range of procedures including vascular and fracture work. Write, James M. Stern, M.D., 600 Vista Court, Waynesboro, PA 17268.

GENERAL/VASCULAR. August '84. Age 33. Nat'l bds. AB cert. MD, University of Puerto Rico; Int. and Res., S.U.N.Y. at StonyBrook; Fellowship, Lehigh Valley Medical Center. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Ruben J. Delgado, M.D., 7514 Oriental Trail, San Antonio, TX 78244.

UROLOGY

Presently available. Age 34. FLEX. AB elig. MD, University of the East, Philipines; Int., Union Memorial Hospital, Baltimore, MD; Res., Franklin Square Hospital, Baltimore, and (Urology) Geisinger Medical Center, Danville, PA. Prefers group or associate type practice in a medium-sized suburban community. Write, Joel K. Barrientos, M.D., 28 Cherry St., Danville, PA 17821.

July '84. Age 31. Nat'l bds. AB elig. MD, SUNY Stony Brook, NY; Surgical Int. and Res., St. Vincent's Hospital, NYC; Urological Res., Beth Israel Hospital, NYC. Prefers group, assoc., institutional or industrial type practice in a small to medium-sized community. Write, Susan G. Kaplan, M.D., 353 East 17th Street, Apt. 9C, New York, NY 10003.

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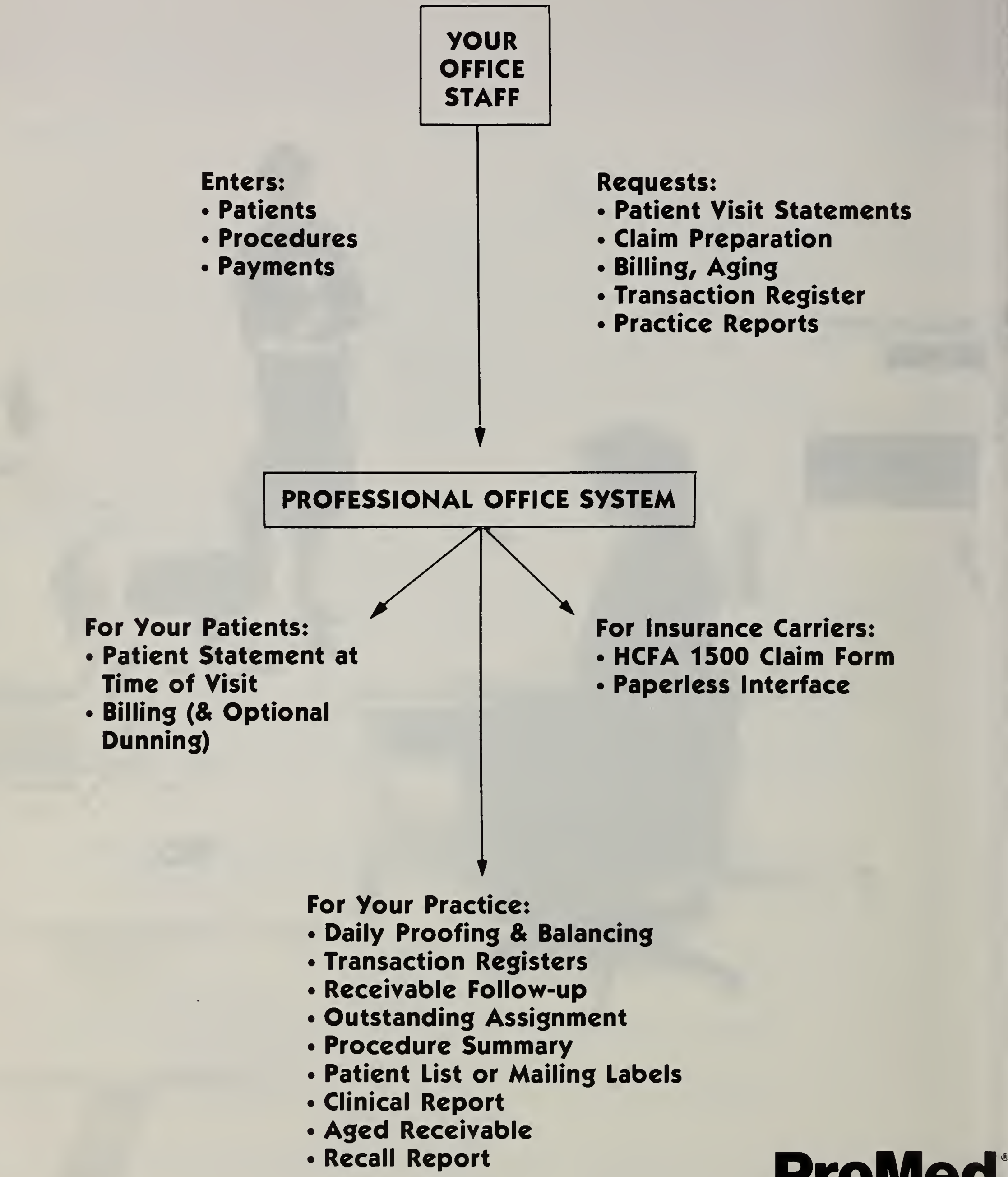

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Bacterial Tracheitis—Déjà Vu

JACOB HEN, JR., M.D.

Bacterial tracheitis is a localized bacterial infection in which purulent secretions occlude the upper airway resulting in a syndrome with clinical and laboratory features common to both laryngotracheobronchitis and epiglottitis. Prior to the 1940's, the majority of cases of acute laryngotracheobronchitis were apparently bacterial tracheitis with a mortality reported as high as 40%.[1-2] After World War II, acute laryngotracheobronchitis changed and was primarily caused by viral agents while bacterial tracheitis either disappeared or was substantially modified by antibiotic use. Since 1979, 60 cases of bacterial tracheitis have been reported in North America.[3-9] Because of the occurrence of acute respiratory arrest in many cases, bacterial tracheitis must be recognized early and prompt management instituted to prevent catastrophic upper airway obstruction as seen with epiglottitis.

In this report, two cases of bacterial tracheitis seen at Bridgeport Hospital over the past nine weeks are presented to alert physicians of its presence since none has been reported in this area. In addition, the clinical presentation and management of bacterial tracheitis are reviewed.

Case Reports

Case 1: R.S. was a 21-month-old male with a seven-day history of cough, fever to 40 °C and progressive stridor. He was seen by his pediatrician three days prior to admission for a right upper lobe pneumonia and was placed on ampicillin. A lateral neck roentgenogram was normal at that time. The illness continued and he was brought to a local emergency room in severe respiratory distress with a temperature of 40.6 °C. While being examined, the child had a respiratory arrest. During intubation, white, purulent material was found in the trachea. After placement of a 4.0 mm uncuffed endotracheal tube and stabilization, the child was transferred to the Pediatric Intensive Care Unit at Bridgeport Hospital where upon admission the child was comfortable, breathing on his own with stable vital signs and a temperature of 40 °C. The admission chest radiograph demonstrated proper tube placement and infiltrates in the left lower and right upper lobes. Admission complete blood count revealed a white count of 14,300 with a left shift (35% bands). Gram stain of the tracheal material showed numerous polymorphonuclear cells and gram negative pleomorphic rods. A complete sepsis evaluation, arterial blood gases, and routine admission studies were normal and he was placed on ampicillin and chloramphenicol for presumed Haemophilus influenzae bacterial tracheitis.

The child was maintained on a T-tube in room air and remained comfortable requiring no sedation. The tracheal secretions grew Haemophilus influenzae type B sensitive to ampicillin, and chloramphenicol was discontinued on the third day of hospitalization. On the fourth day, R.S. was clinically stable with minimal tracheal secretions and a substantial air leak around the endotracheal tube, and he was successfully extubated. His white count and temperature had returned to normal. R.S. was discharged on the eighth hospital day with a normal chest radiograph to complete a ten-day course of ampicillin. At two-week followup, he was asymptomatic and doing well.

Case 2: J.A. was a 12-month-old male who was seen one day prior to admission with a one-day history of mild stridor and low grade fever. A diagnosis of otitis media and viral croup was made, and he was sent home on ampicillin, cool mist, and supportive therapy. He returned the following morning in moderate respiratory distress with a temperature of 40 °C and was admitted with a diagnosis of croup syndrome and otitis media. A lateral neck radiograph was normal and his chest radiograph showed subglottic narrowing consistent with laryngotracheobronchitis. His white count was 24,600 with 26% bands. J.A. was placed in a mist tent with oxygen, on intravenous fluids, ampicillin, and antipyretics. His temperature decreased to 37.5 °C. An arterial blood gas in 30% oxygen was: pH = 7.36, PaCO2 = 42 torr, PaO2 = 160 torr. During the next three hours, he deteriorated with no response to systemic steroids and racemic epinephrine administered via nebulizer, and he was transferred to the Pediatric Intensive Care Unit. Shortly after transfer, the child had a three-minute generalized seizure when his temperature rose to 40.3 °C. A sepsis and metabolic evaluation was normal and a percutaneous radial artery line was placed for monitoring. Arterial blood gases revealed a progressive respiratory acidosis and elective intubation was planned. During intubation, thick, yellow-white, purulent material was seen completely occluding the trachea, and a 3.5 uncuffed endotracheal tube was placed without complications. Immediately following intubation and suctioning of the trachea, the child became comfortable and his blood gases returned to normal. A gram stain of the tracheal secretions revealed abundant polymorphonuclear cells and gram negative cocci. Parenteral oxacillin and chloramphenicol were started for presumed bacterial tracheitis. He was maintained comfortably on a T-tube in room air and within 24 hours his fever and white blood count returned to normal. The tracheal culture grew alpha hemolytic and non-hemolytic strep and neisseria species. All other cultures (including subsequent viral cultures) were negative. Chest radiographs were all normal with proper tube placement. By the fifth hospital day, he was clinically stable, secretions were minimal, and there was adequate leakage around the endotracheal tube to allow for a successful extubation. J.A. completed an uneventful ten-day course of parenteral oxacillin and chloramphenicol and was discharged.

Discussion

Two cases of bacterial tracheitis in children are described. In both cases the diagnosis was not initially suspected and only made at the time of intubation for respiratory failure.

Bacterial tracheitis has recently been reported in children from one month to nine years of age from other areas of North America. As with other respiratory illnesses in children, there appears to be a higher incidence among males.[4-8] The clinical presentation has features of laryngotracheobronchitis and epiglottitis (Table 1). Children often present with a prodrome of one to four days of progressive stridor, barking cough, and a high fever (>39 °C) which is unresponsive to standard croup treatment (cool mist, oxygen, racemic epinephrine, steroids). There is usually no cyanosis, hoarseness, drooling, or

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Table 1
CLINICAL FEATURES OF BACTERIAL TRACHEITIS,
LARYNGOTRACHEOBRONCHITIS AND EPIGOLOTTITIS [3,5,7,9]

	Bacterial Tracheitis	*Laryngotracheobronchitis*	*Epiglottitis*
Number	32	67	35
Mean Age (months)	32	33	42
Age Range	1 month-9 years	8 months-5 years	17 months-5 years
Duration of Illness Prior to Admission (hours)	24-96	12-78	2-48
Clinical Symptoms			
Stridor	Common	Common	Uncommon
Barking Cough	>50%	>60%	Uncommon
Mean Temperature (°C)	39.2	37.8	38.6
Hoarseness	None	20%	Uncommon
Wheezing	10%	5%	None
Cyanosis	10%	10%	20%
Dysphagia	None	None	10%
Drooling	None	None	10%
WBC range/mm	8,000-20,000	5,000-11,000	16,000-22,000
PMNs range (%)	40-80	40-80	60-95
Mean Bands (%)	30	7	30
Roentgenographic Findings			
Subglottic Narrowing	60-100%	90-100%	None
Enlarged Epiglottis	Rare	None	100%
Pneumonia on Admission (%)	>50	10	<30
Pneumonia During Hospitalization	100%	Common	Rare
Response to Vaponephrine (%)	0	>95	0
Positive Bacteria Tracheal Culture (%)	100	0	>70
Positive Blood Culture (%)	0	0	>80
Intubation (%)	65	3	99
Tracheostomy (%)	30	<1	1
Cardiorespiratory Arrest	25%	N/A, Rare	N/A, Increased Risk
Mean Duration of Hospitalization (Days)	21	7	5

PMN—Polymorphonuclear Leukocyte
N/A—Not Available for Data in References—3,5,7,9

dysphagia. Similar to epiglottitis, there is a significant risk of sudden respiratory arrest in children with bacterial tracheitis. The white blood count shows a leukocytosis with a predominence of polymorphonuclear cells and a shift to the left suggesting a bacterial infection. Roentgenograms may be helpful to rule out epiglottitis or foreign body aspiration, however the diagnosis of bacterial tracheitis cannot be made radiologically. The lateral neck radiograph is usually normal and there is often subglottic tracheal narrowing and pulmonary infiltrates on the chest radiograph. Because of these radiological findings, Sofer et al suggest a more proper name for this illness to be bacterial laryngotracheopneumonia.[7] Liston recently reported a case with both bacterial tracheitis and epiglottitis caused by Haemophilus influenzae type B with a classic lateral neck radiograph for epiglottitis and a very swollen, red epiglottis and purulent tracheal secretions on direct laryngoscopy.[9] Until recently, only bacteria have been implicated as pathogens causing bacterial tracheitis. However, Liston et al reported 12 cases of bacterial tracheitis seen between October and November 1981, six of which they isolated parainfluenza virus as well as bacteria from tracheal secretions.[9] They suggest that perhaps during viral croup the primary viral infection may predispose some children to a secondary bacterial infection of the upper airway leading to bacterial tracheitis. Except for the one case with both epiglottitis and bacterial tracheitis, the only positive bacterial cultures have come from tracheal secretions to suggest that bacterial tracheitis is a localized infection of the tracheobronchial tree. The bacteria isolated from tracheal secretions in recent reports in order of frequency are summarized in Table 2. The reason for the prevalence of Staphylococcal infection is not known. The role of normal mouth flora (as seen in our second case) has not been determined yet.[9]

The diagnosis of bacterial tracheitis can only be made by direct visualization of the trachea (laryngoscopy or bronchoscopy) where inflammation, edema, pustules, exudate, and/or an exudative membrane may be found.[4-9] Patients require an artificial airway which should be placed electively by experienced personnel under controlled conditions. Liston et al recommend tracheostomy rather than endotracheal intubation (in contrast to the current recommendation of endotracheal intubation for epiglottitis and severe viral laryngotracheobronchitis).[9] In their series of 17 cases with an overall complication rate of

Table 2
MICROBIOLOGIC FINDINGS IN BACTERIAL TRACHEITIS [3,5,7,9] (Order of Frequency)

Coagulase-positive Staphylococcus aureus (60%)
Haemophilus influenzae type B
Streptococcus, group A β-hemolytic
α-hemolytic streptococcus species
Neisseria species
Escherichia coli
Others

41%, there were fewer complications such as pneumothorax, accidental extubation, and cardiorespiratory arrest in those children with tracheostomies compared with the group with no artificial airway or the group with endotracheal tubes. We may need a larger number of cases of bacterial tracheitis before the issue of intubation versus tracheostomy can be resolved. The most common extrapulmonary complication is central nervous system hypoxia secondary to acute upper airway obstruction. Many children have spent up to three weeks in the hospital because of prolonged intubation and complications. Since 1979, there have been three deaths out of 60 reported cases (5% mortality).[9]

Our two cases are typical of bacterial tracheitis. The first case presented with a prodrome of high fever, stridor, and pneumonia suddenly having a respiratory arrest while being examined. The second case was thought to have viral croup with otitis media and high fever unresponsive to standard croup therapy, requiring intubation for progressive respiratory failure. The clinical picture of croup syndrome in the spring or summer should make one suspicious of epiglottitis, bacterial tracheitis, foreign body aspiration, and other less common problems. Roentgenograms were of little help except to rule out epiglottitis, radio-opaque foreign body, or retropharyngeal abscess. Compared to the cases reported in the literature our patients had a very short and uncomplicated hospital course.

Bacterial tracheitis is an old disease which has reappeared in North America in recent years as a cause of severe upper airway obstruction to be differentiated from other causes of croup syndrome in children. It has specific clinical and laboratory features to alert physicians to suspect it early when evaluating such children. Children who present with a clinical picture of epiglottitis, foreign body aspiration, or viral laryngotracheobronchitis unresponsive to standard croup treatment (especially with a high fever and leukocytosis with a left shift) and children in severe, acute distress should have minimal manipulation to avoid sudden respiratory arrest. Immediate laryngoscopy/bronchoscopy should be performed, preferably in the operating room. If epiglottitis, bacterial tracheitis, or severe viral laryngotracheobronchitis are found, an artificial airway should be placed and further management planned accordingly. Management recommendations for bacterial tracheitis are summarized in Table 3. The choice of intubation or tracheostomy at present should be determined by the expertise and facilities available until we have more data. A semi-synthetic penicillin and chloramphenicol, should be started pending tracheal gram stain and cultures. Admission to a pediatric intensive care unit is advisable. Admission and followup chest roentgenograms are required to check for tube placement and pneumonia. The need for supplemental oxygen and mechanical ventilation should be determined clinically and by frequent blood gas monitoring. Meticulous pulmonary toilet and chest postural drainage should be started early. The duration of artificial airway placement depends on the quantity of pulmonary secretions. Extubation should only be attempted when secretions are minimal, there is a substantial air leak around the airway, and standard clinical and physiological criteria are met. Antibiotics should be given for at least 10 days. Early and close neurologic evaluation for hypoxic central nervous system damage is recommended. In cases of Haemophilus influenzae type B bacterial tracheitis, rifampicin prophylaxis should be considered for the patient and age appropriate contacts (as with other serious Haemophilus influenzae type B infections) until more is known about this infection.

Table 3
MANAGEMENT OF BACTERIAL TRACHEITIS

1. Early suspicion of bacterial tracheitis.
2. Minimal patient manipulation.
3. Prompt laryngoscopy/bronchoscopy under controlled conditions.
4. Artificial airway placement (tracheostomy or intubation).
5. Admission to a pediatric intensive care unit.
6. Gram stain and cultures of tracheal secretions.
7. Parenteral semisynthetic penicillin and chloramphenicol started immediately. Minimal 10-day course of appropriate antibiotic(s) depending on culture results.
8. Admission and followup chest roentgenograms.
9. Oxygen administration and mechanical ventilation as required by clinical course and arterial blood gases.
10. Meticulous pulmonary toilet and chest postural drainage.
11. Criteria for extubation:
    a) Minimal secretions
    b) Adequate leak around airway
    c) Standard clinical and physiological extubation criteria
12. Close evaluation for evidence of CNS hypoxia.
13. Early consideration of nutritional support.
14. Consider rifampicin prophylaxis of patient with Haemophilus influenzae type B bacterial tracheitis and age appropriate contacts.

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Pyogenic Liver Abscess: Needle Aspiration and Antibiotic Therapy

HAROLD B. HAWKINS, M.P.H., M.D., DOROTHY C. CINTI, M.D.

AND ROBERT W. LYONS, M.D.

ABSTRACT—Two patients with hepatic abscesses are presented. Both were successfully treated with percutaneous thin needle aspiration and antibiotic therapy. The evolving therapeutic approach to hepatic abscess is discussed.

Introduction

Over the past 45 years there have been continual changes in the methods of diagnosis and treatment of hepatic abscesses.[1-2] Recent reports emanating from radiology and surgery departments emphasize the use of percutaneous catheter drainage.[3-4] In contrast, current medical literature emphasizes the viability of closed aspiration and antibiotic therapy.[5-9] For this reason, it seems appropriate to present the success of the later therapeutic approach in a publication which embraces all medical specialities.

We have recently had occasion to perform ultrasonically guided percutaneous needle aspiration on two patients with liver abscesses. Both were subsequently treated with appropriate antibiotic therapy with no need for either catheter or open surgical drainage.

Case Reports

Case 1: A 36-year-old Puerto Rican man presented with a three week history of fever, severe right upper quadrant pain, nausea, vomiting and anorexia. On admission his temperature was 102.7 degrees Fahrenheit and his pulse was 120. Physical examination revealed mild hepatic enlargement, guarding of the right upper quadrant, and a 5 cm area of point tenderness along the right costal margin in the mid clavicular line.

The laboratory findings included a WBC of 13,600 with 53% neutrophils and 28% bands. Hemoglobin and hematocrit were 11.8/35.6. Alkaline phosphatase was increased to 182 IU/L (normal 20-80) and liver transaminases were mildly elevated. Blood cultures were negative.

A technetium 99m sulfur colloid liver scan revealed a large focal defect in the medial aspect of the left lobe of the liver (Figure 1A). On ultrasonic examination this was a 5 cm hypoechogenic mass with central liquification (Figure 1B). The patient was started on ampicillin and tobramycin but he continued to spike daily temperatures to 102 degrees.

On the fourth hospital day he was referred for consideration for percutaneous aspiration and/or drainage. An ultrasonically guided percutaneous aspiration of the hepatic lesion with a 22 gauge thin walled UMI needle yielded 27 cc of pus and resolution of the sonographically visible central collection of fluid. By the day after the aspiration, the patient was afebrile, had minimal right upper quadrant tenderness and had a markedly improved appetite.

Culture of the aspirate grew multiple organisms including *Fusobacterium sp., Hemophilus paraphrophilus,* and streptococcus (group C). In accordance with sensitivities, the tobramycin was discontinued and the ampicillin dosage was increased.

By the eighth hospital day, the patient's WBC count had returned to normal. He was continued on intravenous ampicillin in the hospital for a total of 20 days with complete clinical recovery. This was followed by four weeks of oral ampicillin coverage as an outpatient. Two months after termination of antibiotic therapy, he remained clinically asymptomatic.

Sequential follow-up ultrasonic scans of the liver showed progressive decrease and ultimate resolution of the area of hepatic abnormality (Figure 1C).

Case 2: A 34-year-old Jamaican male presented with a two month history of diarrhea, abdominal pain, fever, and weight loss. Imaging with technetium 99m sulfur colloid, computerized axial tomography and ultrasonic scans, revealed two focal liver masses, one measuring 13 cm and the other 4 cm in diameter. The larger mass demonstrated a small eccentric area of liquification (Figure 2A). Percutaneous aspiration of the liver was requested in order to ascertain whether these represented an infectious process or neoplastic disease. The aspirate was performed with ultrasonic guidance with a 22 gauge thin walled UMI needle and yielded 1 cc of pus from the area of liquification and fragments of friable tissue from the surrounding mass. Cytologic

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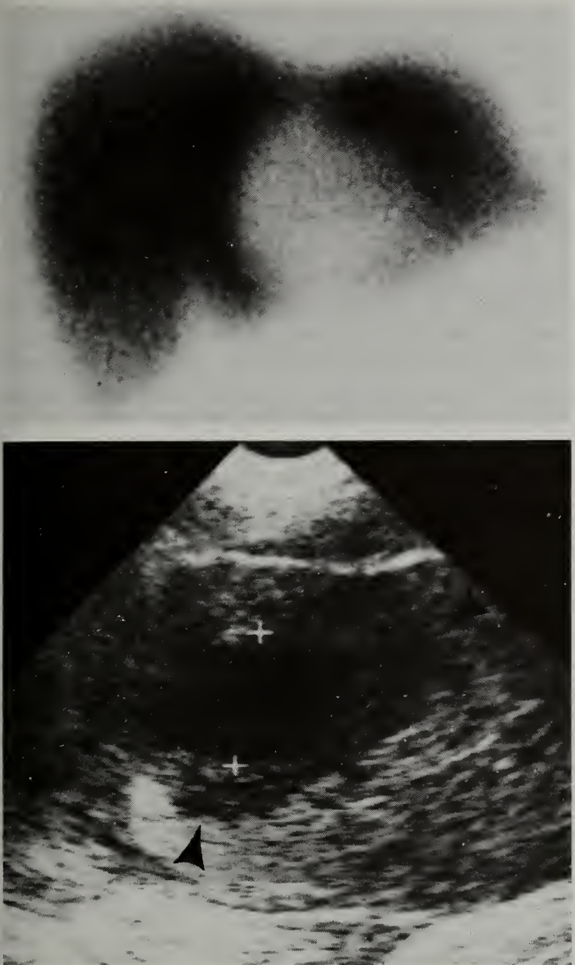

Figure 1, Case 1
A: ^{99m}Tc sulfur colloid scintigram shows large focal liver defect. B: Corresponding sonogram reveals 5 cm hypoechoic mass (arrows) with central sonolucency (+). C: Sonogram 2 months after aspiration is normal.

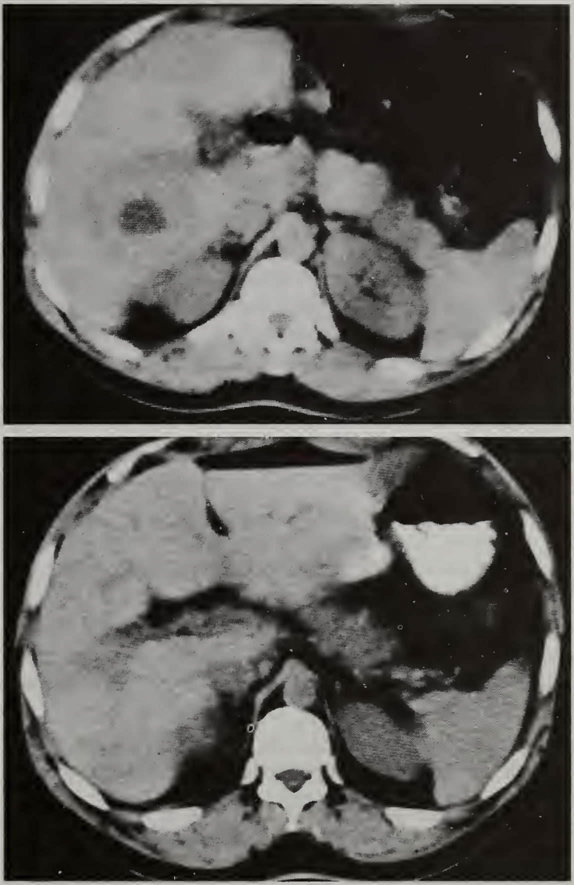

Figure 2, Case 2
A: Unenhanced CT scan shows one of two liver masses. The area of decreased attenuation contained liquid material which was aspirated. B: 5 months after aspiration and antibiotic therapy, the CT scan is normal.

evaluation showed no evidence of tumor. Clinical concern of an underlying neoplasm persisted, however, and a laporotomy was performed. This revealed multiple inflammatory masses in the liver and chronic appendicitis. Presumably, the appendix was the source of hepatic seeding. The only positive cultures during the course of the hospitalization were those obtained from the percutaneous needle aspiration. These grew *Fusobacterium sp.*, and an alpha-hemolytic streptococcus for which the patient was treated with intravenous clindamycin for a total of four weeks in the hospital and oral penicillin for a total of five months as an outpatient. He had a gradual complete clinical recovery and resolution of liver imaging abnormalities (Figure 2B).

Discussion

Pyogenic liver abscess historically has been a serious clinical problem with high mortality and morbidity. Since Oschner's landmark article in 1938,[1] there has been gradual evolution in the preferred modes of therapy. Initially, treatment was surgical incision and drainage via an extraperitoneal approach.[1-2] With the advent of antibiotics, transperitoneal incision and drainage with antibiotic coverage was deemed acceptable when extraperitoneal access was not possible.[2] Changes over the past 15 years have been largely attributable to advances in imaging. The development of technetium sulfur colloid liver scanning, gallium scanning, ultrasound, and computerized axial tomography has provided progressively more sensitive and accurate imaging. This has resulted in improved prognosis due to both earlier diagnosis and more accurate surgical approach.[2]

In the past five years, CT and ultrasound have been used with increasing frequency to guide percutaneous catheter drainage of various organs and fluid collections. Percutaneous catheter drainage with concomitant antibiotic therapy has been successful in treating liver abscess, has an acceptable morbidity and mortality, and provides an alternative to surgical therapy.[3-4] It is considered by some to be preferred to open incision and drainage in the patient who does not require surgery for complicating processes such as appendicitis, biliary obstruction, etc.[4]

However, in the midst of the current radiologic enthusiasm for all forms of percutaneous catheter therapy, the radiology literature has failed to acknowledge the less invasive, safer, and at least equally successful approach of simple percutaneous needle aspiration of the liver and appropriate antibiotic treatment. This approach was initially reported by McFadzean in 1953.[10] His success was impressive (14 of 14 cases) and he had no complications, but the method never became popular.

More recently, reports in the medical literature describe remarkable success using 22 to 18 gauge needles for diagnostic and/or decompressive ultrasound guided aspiration of the liver followed by antibiotic therapy. These series describe success in 15 out of 15,[5] 5 of 6,[6] 7 of 7,[8] and 4 of 5[9] patients treated with this approach. In some of these patients, partial or complete decompression was achieved by aspirating as much fluid as possible. In others, the aspiration was performed solely for diagnostic purposes with no attempt to remove more than a few cc's. The approach has been useful with solitary as well as multiple abscesses[5,7] and with lesions as large as 12 cm in diameter.[7] There are no reported complications. Although these reports include some additional cases of success with antibiotic therapy alone,[6,9] the use of aspiration provides the advantages of: (1) Ruling out the possibility of an underlying neoplasm, an uninfected cyst, or a non-pyogenic infection such as an amebic abscess; (2) Providing material for culture from the abscess itself. As in both of our cases, blood cultures are often negative.[7,8,10] Even when blood cultures are positive, there are frequently multiple offending organisms within the abscess cavity and they may not all be cultured from the blood.[8]

In conclusion, the high success rate, relatively noninvasive approach and absence of complications in our own cases and those reported in the medical literature, suggest that the initial therapeutic approach in patients with hepatic abscess should be a simple ultrasound guided needle aspiration followed by antibiotic therapy which is based on culture of the aspirate. Only if the patient fails to respond to this approach, does percutaneous catheter drainage and/or surgical incision and drainage need be considered.

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Severe Thrombocytopenia Following the Administration of Aminoglutethimide

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Aminoglutethimide (Cytadren), a drug initially introduced in 1958 as an anticonvulsant, was later found to inhibit adrenal gland biosynthesis of steroids. [1] More recently this compound has been used successfully to perform a reversible medical adrenalectomy in women with advanced breast cancer. [2] Although hematologic side effects appear to be infrequent with the use of aminoglutethimide, I wish to report a case of severe potentially life threatening thrombocytopenia.

Case Report

A 63 year-old postmenopausal woman presented in June 1978 with an egg size mass in the right axilla. A mammogram revealed a 2.5 cm lesion in the upper outer quadrant of the right breast. A wide local excision of the primary breast mass and axillary node dissection revealed infiltrating duct mammary carcinoma with evidence for 24/34 positive right axillary lymph nodes. A bone scan revealed osseous metastases while a chest x-ray and liver scan were negative. Estrogen binding receptors from the primary tumor specimen were positive at 72 femtomoles/mg. cytosol protein and progesterone receptors were positive at 88 femtomoles/mg. cytosol protein. A complete blood count, differential and platelet count were normal and tamoxifen 10mg. orally twice a day was begun with evidence for disease stabilization.

With progression of the osseous metastases, tamoxifen was stopped in February 1980. Four weeks later (March 25, 1980), aminoglutethimide 250mg. orally four times a day was begun with hydrocortisone replacement at a time when the blood urea nitrogen, creatinine and liver chemistries were normal. A random glucose was elevated at 179 mg/dl consistent with the patient's known type II diabetes mellitus. The patient was not taking insulin or oral hypoglycemic drugs. On March 25, 1980, a white count was 7000/mm^3 with a normal differential, hemoglobin 14.2gm/dl and platelet count 292,000/mm^3. On April 1, 1980, a white count was 11,400/mm^3 with a normal differential, hemoglobin 15.4gm/dl and platelet count 306,000/mm^3. On April 8, 1980, the patient presented with spontaneous epistaxis and extensive petechiae over the buttocks and lower extremities. At that time, a white count was 7,600/mm^3 with a normal differential, hemoglobin 14.6 gm/dl and platelet count 13,000/mm^3, repeated 19,000/mm^3. A peripheral blood smear revealed greatly reduced platelets with occasional megathrombocytes. A bone marrow aspirate and biopsy from the left posterior iliac crest revealed findings of mildly increased megakaryocytes but no other abnormalities except for reduced iron stores. Blood urea nitrogen creatinine, liver chemistries and clotting studies were normal. Ten units of random donor platelets were transfused and prednisone 20 mg orally three times a day was begun. Aminoglutethimide and hydrocortisone were stopped.

On April 11th, the complete blood count was normal (platelets 280,000/mm^3) and on April 18th, off prednisone, the platelet count was 363,000/mm^3. Subsequently, the patient was treated sequentially for her progressive osseous metastases with fluoxymesterone, megestrol acetate, diethylstilbesterol, a combination of cyclophosphamide, methotrexate and 5-fluorouracil and most recently with doxorubicin. Platelet counts have remained normal during further hormonal additive treatments and have demonstrated reversible changes with cytotoxic drugs.

The patient described above developed sudden onset thrombocytopenia apparently secondary to aminoglutethimide administration for breast cancer. The mechanism of the drug induced thrombocytopenia is unclear but might involve an innocent bystander reaction or possibly drug immune complex formation with subsequent macrophage clearing of the abnormally coated platelets. In this patient, aminoglutethimide did not appear to directly affect the bone marrow. In a review of the use of aminoglutethimide for the treatment of postmenopausal women with breast cancer, investigators from the Milton S. Hershey Medical Center made no mention of any hematologic side effects in a group of 147 patients. [2] However, these investigators had previously reported a single episode of reversible pancytopenia secondary to aminoglutethimide marrow injury in a patient receiving this drug. [3] Asbury et al reported a 12 percent incidence of leukopenia and a 4 percent incidence of thrombocytopenia among 63 women treated with aminoglutethimide. [4] However, the severity and clinical setting of the hematologic side effects was not discussed in that paper. Likewise, Ciba-Geigy, the manufacturer of aminoglutethimide, has on record case reports of apparent drug related leukopenia, thrombocytopenia and pancytopenia but the incidence and relationships between drug and exposure and the onset of the hematologic disturbances is unclear. [5] A report of reversible glutethimide induced thrombocytopenia has been published

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and appears similar to the current case.[6] A bone marrow examination from this patient was "non-diagnostic" as it was taken from a previously radiated area of bone marrow. More recently, a report of irreversible thrombocytopenia following the administration of aminoglutethimide has appeared but a bone marrow aspirate and biopsy were not performed.[7]

In conclusion, aminoglutethimide has been shown to have a clear cut cause and effect relationship to the development of potentially life threatening thrombocytopenia. Although the incidence of this side effect is probably low, it would be prudent to obtain complete blood counts and platelet counts frequently during the initial four weeks of administration of aminoglutethimide.

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Sexual Functioning During Pregnancy: A Brief Cross-Cultural Perspective

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Animal Data

Yerkis[1] in 1939 reported that sexual intercourse in the pregnant chimpanzee was sporadic and typically not an indication of the pregnant chimp's sexual desire. The female was often accommodating to the male in order to avoid having a fight.

In most mammalian species females do not seek intercourse during pregnancy. If pressured by the male, and if in confined physical conditions, female primates will submit.[2-4]

Developing Societies

Ford and Beach[5] reported on the occurrence of sexual intercourse during pregnancy in 60 primitive societies. Seventy percent of societies permitted intercourse during the second month of pregnancy, 63% during the third to fifth months, 50% during the sixth to seventh months, 40% during the eighth and only 25% during the ninth.

The major reason for coital abstinence during pregnancy was to prevent injury to the fetus.

The Mourgines fear that intercourse during pregnancy will cause the child to be stillborn. Infant mortality among them is high enough to explain this anxiety. A

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This paper was presented on October 21, 1982 at the Beijing Railway General Hospital. A Delegation from the American Society for Psychoprophylaxis in Obstetrics (ASPO/Lamaze) traveled to China to exchange ideas with childbirth educators, nurses and obstetricians.

less restrictive policy is found among the Crow Indians where the wife has to refuse intercourse only from the time she perceives fetal movements. Consequently, intercourse during the first five months of pregnancy is permitted. The Ifugas and Tanalas do not impose any sexual restriction during pregnancy. Gebhard, previous director of the Kinsey Institute, has stated that among the Azanda Tribe in Africa the father's sperm is considered necessary for the growth of the embyro. As a consequence sexual relations during pregnancy are strongly encouraged.

Modern Studies

In Kinsey's landmark publication "Sexual Behavior In The Human Female" no specific mention was made of the affect of pregnancy on female sexual functioning.[6] Masters and Johnson[7] in 1966 reported on sexual changes during pregnancy utilizing two study groups. In the first group of six females sexual functioning was directly observed and measured in the research laboratory while in the second group of 111 females regular verbal reports on sexual functioning were obtained as the pregnancies progressed. Accordingly, they found that sexual frequency decreased in the first trimester (mostly due to psychological factors), increased in the second trimester (allegedly due to increased pelvic congestion) and decreased in the third trimester due to physical discomfort. In 1969 Bartova et al reported on the sex life of 500 pregnant Czech women and found a marked decrease in both sexual interest and activity for many pregnant females. In 1970 Prochazka and Cernoch[9] also reporting on Czechoslovakian women found that many continued having intercourse during pregnancy for fear that their husbands would become unfaithful.

In 1972 a textbook on "Modern Perspectives In Psycho-Obstetrics"[10] containing more than 590 pages did not report on the relationships between sexuality and pregnancy.

In 1973 Solberg et al[11] reported on interviews of 260 females just after childbirth. Retrospectively it was found that intercourse decreased in a linear fashion once pregnancy was discovered; orgasmic ability decreased and sexual interest decreased.

They also provided for the first time normative data on masturbation, genital stimulation and oral genital stimulation during pregnancy. In the two years before the present pregnancy 16% of 259 females had masturbated to orgasm. During the one year prior to pregnancy 14% masturbated to orgasm and during the pregnancy only 7.2% did. Stimulation of the female genital area by the partners hand in an attempt for her to be orgasmic—was practiced by 45% or 118 of the women during a baseline period two years pre-pregnancy. During the one year period before the pregnancy only 35% used this form of sexual stimulation, and during pregnancy, only 27% did. Interestingly the orgasm rate from hand stimulation did not vary significantly during the pregnancy.

Oral genital stimulation in an attempt for the female to be orgasmic was practiced by 39% or 99 women during the baseline period two years before the pregnancy. During the one-year period pre-pregnancy 34% of the women received oral genital stimulation and during pregnancy only 20% did. Unlike manual stimulation the orgasm rate from oral genital stimulation did decline during pregnancy.

Kenny[12] in 1973, using a questionnaire retrospectively on a nonrandom sample of 33 females, found that desire, frequency, enjoyment and orgasm were "about the same" during the first two trimesters whereas desire, frequency and enjoyment decreased during the third trimester. Tolor and DiGrazia[13] administered a questionnaire prospectively to 161 pregnant females that were almost equally divided among the three trimesters. There was a "... characteristic decline both in sexual interest and in sexual activity as the pregnancy progresses." There was also a decline in the orgasm rate and the authors concluded that sexual reactivity is extremely sensitive to pregnancy. Pasini[14] in 1977 interviewed 100 women after childbirth at the Maternity of Geneva. This retrospective study found that sexual desire, frequency and satisfaction diminished progressively as pregnancy proceeded and confirmed the findings of Tolor and DiGrazia. Pasini also found that sexuality declined much more for the primiparae than for the multiparae.

Hollender and McGehee[15] studied the women's desire to be held during pregnancy and whether or not that desire was influenced by race. Numerically 23 out of 50 females, or 46%, had an increased desire to be held, 8 out of 50, or 16%, had less of a desire to be held and for 19 out of 50, or 38%, the desire was unchanged. Their conclusions were that "... more than one-half of the women noted a change in their wish to be held, and of those who did, approximately 3 out of 4 reported an increased desire." The body contact scores tended to be higher for white females but this could be due to marital and not racial factors as only 3 out of 25 white females were not married and 14 out of the 25 black females were not married.

Conclusions

Four studies (Solberg, Kenny, Tolor and Pasini) have not confirmed the original findings of Masters and Johnson that there is an increase of all of the major parameters of sexual behavior during the second trimester of pregnancy.

Pasini did confirm Masters and Johnson's report that parity affected sexuality and that the decline was mostly among primiparae. Future research should include longitudinal studies using the same research subjects before, during and after pregnancy while also obtaining information from the partner.

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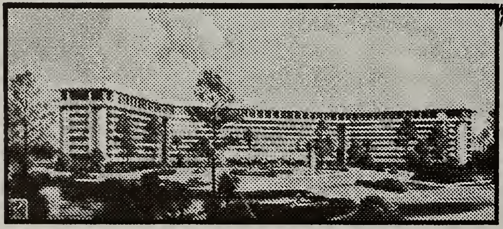

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Important Advances in Clinical Medicine

Epitomes of Progress—Ophthalmology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in ophthalmology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in ophthalmology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Ophthalmology of the California Medical Association and the summaries were prepared under its direction.

Steroid-Induced Glaucoma

Steroid-induced increase of intraocular pressure has been described for more than 30 years; however, it remains a cause of visual loss and iatrogenic glaucoma. Unfortunately, steroid drops are often prescribed for relatively minor conditions such as blepharitis or eye irritations, conditions for which steroids are often unnecessary. Steroids decrease outflow facility, resulting in a condition simulating primary open-angle glaucoma. If prolonged intraocular pressure elevation occurs, damage results to the optic nerve with irreversible loss of visual field.

Both endogenous and exogenous steroids may induce pressure elevations in susceptible persons. Topical, periocular and systemic steroid medications are involved in the vast majority of cases. Even steroid preparations applied to the skin away from the eye may induce elevations of intraocular pressure. Susceptibility to topical steroids has been tested extensively. From these studies a substantial percentage (33%) of the population were found to be at risk, particularly patients with preexisting open-angle glaucoma and their first-degree relatives. In addition, persons with myopia and those with diabetes mellitus are also at increased risk. The degree of pressure elevation depends on individual susceptibility and the concentration, duration and frequency of the dose. Increased intraocular pressure may occur as early as one to two weeks or as late as months to years after initiation of therapy.

The clinical spectrum of corticosteroid-induced glaucoma varies with a patient's age. In infants often treated with topical steroids as part of an antibiotic-steroid combination, the disease simulates congenital glaucoma with an enlarged eye and corneal edema. In older children and adults, the disorder resembles primary open-angle glaucoma, and is often asymptomatic.

The most effective treatment of steroid-induced glaucoma is discontinuation of the corticosteroid. Within a few days to weeks, a prompt reduction of intraocular pressure occurs. Occasionally the increased pressure persists. If this occurs or if the steroid therapy must be continued, standard antiglaucoma medications may lower the pressure. If unsuccessful, laser or intraocular surgical treatment may be necessary for glaucoma management.

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Macular Degeneration

Macular degeneration is the leading cause of new blindness in the United States and accounts for 14% of cases of new blindness in persons older than age 65 years. Age-related macular degeneration covers a wide spectrum of clinical disease and visual dysfunction. The

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prevalence of this disease in the older-than-50-years age group is very high but only a small percentage of persons have severe visual loss.

Some degree of visual loss is associated with a nonexudative degeneration that is characterized by drusen (yellow deposits on Bruch's membrane) and epithelial derangement of the retinal pigment. The more severe form of degeneration often leading to legal blindness is manifested by hemorrhage and exudation originating from choroidal neovascularization in the macula. This frequently leads to a disciform scar destroying the sensory retina. The pathologic process includes degeneration and breaks in Bruch's membrane (a barrier layer separating the retina and choroid), which allows choroidal vessels to invade the space beneath the retina (choroidal neovascularization) and leak fluid or blood.

Until a recent study by the Macular Photocoagulation Study Group, supported by grants from the National Eye Institute, the treatment of exudative macular degeneration by obliteration of choroidal neovascularization with argon laser photocoagulation had not been proved. A multicenter controlled clinical trial was undertaken in 1980 to answer the question "Is argon laser photocoagulation useful in preventing severe visual loss in eyes with evidence of macular degeneration and a choroidal neovascular membrane outside the fovea?" As few as 1 in 20 patients screened met the eligibility criteria. Of those patients selected, however, by 18 months after entry in the study, 60% of the patients whose eyes were untreated had lost six or more lines of vision compared with only 25% of those whose eyes had been treated. Twice as many patients whose eyes were treated had a visual acuity better than 20/40 at the most recent visit. Persistence of the treatment benefit remains to be determined.

Patients at greater risk, such as those who have lost central vision from exudative macular degeneration in one eye, should be examined periodically. Because persons are in the treatable stage for only a short time after onset of symptoms, it is important for both physicians and patients to be alert for symptoms of distortion, scotoma or blurred vision that may indicate the presence of choroidal neovascularization. Further investigation is being done in hopes of finding other laser wavelengths that may increase the success rate in this vision-threatening disease.

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Severe Systemic Effects From Topically Applied β-Adrenergic Blocking Agents

Recently, β-adrenergic blockers (timolol maleate) have become commercially available for the medical treatment of open-angle glaucoma. These topically applied drugs lower intraocular pressure by decreasing the rate of aqueous humor formation. They are usually effective both alone and in combination with other ocular hypotensive agents in lowering intraocular pressure in an attempt to prevent the optic nerve damage and visual field loss that can ultimately lead to blindness.

Topically applied timolol can be associated with all the side effects characteristic of β-blocking adrenergic drugs. Severe systemic depression, bronchospasm and even death have been described in some patients using this medication. Topically applied β-blockers are contraindicated in patients with a history of bronchial asthma or severe chronic obstructive pulmonary disease, and in patients who have had cardiac failure. Furthermore, special care must be taken to instruct patients in the proper technique of eye-drop installation to minimize systemic absorption from the vascular nasal mucosa.

After installation of a drop, the patient should apply gentle pressure along the side of the nose, over the lacrimal sac. This maneuver enhances intraocular drug penetration and minimizes nasal mucosal absorption.

Allan J. Flach, M.D.

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Endothelial Cell Counts

Endothelial cell counting is one method used to determine the health, longevity and surgical vulnerability of a human cornea. A cornea maintains its clarity if there are enough endothelial cells covering its back surface to continuously pump fluid from it. This one-cell-thick layer of tissue does not replace itself by mitosis. Damaged cells are replaced by neighboring cells stretching to cover the denuded area. The more cells there are the more "reserve" the cornea has to withstand trauma and cell loss. Therefore, it is of clinical importance to know the cell population or cell density of a given cornea.

The technique of endothelial cell counting was first popularized by Bourne and Kaufman in 1975. The procedure is done using a specifically designed endothelial specular microscope that allows high-magnification photography of the actual endothelial cells in vivo. The microscope is calibrated with an internal grid so that the cells in a defined area can be counted much like blood cell counts. The count is reported as cells per sq mm. The microscope is expensive, the technique requires skill and the counting is time-consuming.

The cell density of the human cornea is higher at birth than in old age, the loss of cells being due to attrition. Hoffer and Kraff found that mean cell density in the age range of 40 to 90 years old is 2,400 cells per sq mm and that age was not useful as a predictor of cell density. In one study, in eyes with cell counts of less than 350 cells per sq mm, a cloudy, painful cornea (bullous keratopathy) developed within two years, requiring corneal transplantation. There are many causes of cell loss but surgical trauma is the most common and the most likely in elderly persons. Because patients whose eyes have low counts are at greater jeopardy, it is wise to know the cell density of an eye before considering an intraocular anterior segment operation, such as a cataract extraction with lens implantation. A small percentage of persons have corneas with very low cell density for unexplained reasons and this must be known before a surgical procedure. Because patients who have had a previous eye operation most likely have lower cell density, it is extremely important to do endothelial cell counts on those who are to have a secondary procedure such as a secondary lens implantation.

There are less accurate methods of "estimating" cell density using an ophthalmic slit-lamp microscope. This technique uses a simple estimating comparator and does not require the counting of cells in photographs.

Kenneth J. Hoffer, M.D.

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Corneal Transplantation

Corneal transplantation is an accepted and highly successful therapeutic tool in ophthalmologic surgical procedures. Advanced microsurgical techniques, increased understanding of transplant immunology and the availability of topical corticosteroids have afforded the corneal allograft a degree of success unmatched by transplantation attempts with other tissues. Allograft rejection remains, nonetheless, a problem. Graft rejection attempts occur in about 20% of patients, though the percentage of grafts opacified from immune rejection is considerably smaller.

The mainstay of preventive immunosuppressive therapy has been topical and systemic corticosteroids. The success of these agents depends to a great extent on the vascularity of the recipient bed. The prognosis for graft survival remains only poor to fair in cases in which the host cornea is heavily vascularized.

Despite the success of topical corticosteroids in controlling the graft reaction, they can be associated with potential side effects including steroid-induced glaucoma, cataract, bacterial superinfection and herpetic recurrences. Therefore, alternative methods of immunosuppression have been evaluated. Most recently cyclosporine, a potent T-cell inhibitor that has revolutionized vital organ transplantation when administered either topically or as a retrobulbar injection in the laboratory, has shown promise as a useful immunosuppressive agent in clinical corneal grafting.

Human leukocyte antigen typing has been neither necessary nor practical in corneal transplantation primarily because of the avascularity of the cornea. Recent studies have indicated, however, that in selected heavily vascularized (high-risk) patients, human leukocyte antigen crossmatching or negative crossmatching of circulating lymphocytotoxic antibodies may improve the prognosis for graft survival.

In most cases, however, the prognosis for an optically clear graft is very good. Recipients can be educated in the cardinal danger signs of graft rejection (pain, redness, decreased vision) and, with early recognition and prompt and aggressive local immunosuppression, a clear corneal graft can be maintained.

Mark J. Mannis, M.D.

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Intraocular Lenses for Correction of Aphakia

Before intraocular lenses, the vision of the average postcataract operation patient was corrected with either thick, heavy spectacles or contact lenses. Although most patients can eventually adjust to cataract glasses, problems with depth perception, restriction of peripheral vision and image magnification often remain. Contact lenses eliminate most of these optical problems but require some degree of manual dexterity and a healthy cornea. Despite improvements such as daily-wear soft and extended-wear contact lenses, many patients still fail to achieve satisfactory comfort or visual correction. Intraocular lenses return an eye to an optical condition similar to that preceding the development of the cataract.

The early history of intraocular lens implantation was fraught with problems. Such complications as dislocation, corneal edema, persistent inflammation, secondary glaucoma and endophthalmitis were disturbingly common. Improvements in the finishing, polishing and sterilization of implant lenses and in the surgical techniques have greatly reduced these complications. The specter of serious, unpredictable long-term complications has not materialized although a few lens styles have been associated with late corneal decompensation.

In 1978 the Food and Drug Administration (FDA) classified all intraocular lenses as investigational devices. More than 1 million lens implantations have been monitored. Based on the data from the first 50,000 lenses, the FDA has approved several lens styles from a variety of manufacturers.

Presently, the posterior chamber lens styles are the most popular. Anterior chamber lens styles are also used frequently for both primary and secondary implantations. The use of iris-supported lenses has declined substantially.

In 1982 about 70% of the patients in whom cataract extraction was done in the United States received an intraocular lens implant. Lens implants may now be considered in any cataract patient who has an otherwise healthy eye. Implantation is especially indicated when a patient is not likely to tolerate a contact lens or an aphakic spectacle. An increasing number of patients are receiving "secondary" implants when trials with aphakic contact lenses or spectacles do not prove satisfactory.

Controversy still exists regarding the lower age limit for implantation. Contraindications have been diminishing as experience has improved. Caution is advised in patients with only one eye, severe myopia, uveitis, glaucoma, diabetic retinopathy, corneal endothelial dystrophy or other progressive ocular diseases. Although intraocular lens designs and surgical techniques are still evolving, the improvements accomplished over the past two decades have made lens implantation safe and effective for most cataract patients.

Robert L. Stamper, M.D.

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Ophthalmic Genetics: A New Synthesis

As infectious diseases such as rubella have been brought under control with improved public health measures and immunizations, genetic factors have become increasingly important causes of both congenital and acquired eye diseases, particularly in the pediatric age group. Although accurate statistics are not available in the United States, it is estimated that at least 50% of new cases of legal blindness (20/200, or less than 20 degrees of peripheral vision) in the pediatric age group can be attributed to genetic causes; the economic and social consequences of this visual impairment are devastating. An ophthalmologist assumes a central role in identifying the cause of such visual handicaps and may assist pediatricians or geneticists in establishing a diagnosis in an otherwise perplexing patient. Referral is of particular importance in the detection of unilateral visual impairment, as a child with good vision in one eye may be asymptomatic. The eye is affected relatively early in the course of many genetic metabolic diseases and an ophthalmologist may be the first physician consulted. For example, patients who have Spielmeyer-Vogt disease,a lipopigment storage disorder, may have decreased central vision and ophthalmoscopic findings compatible with juvenile macular degeneration; progressive mental deterioration and visual impairment ensue. For some disorders, such as mannosidosis and Fabry's disease, the ocular manifestations are unique and diagnostic.

The hereditary bases of diseases that affect the eye include all three broad categories: chromosomal aberrations, single gene mutations consistent with Mendelian inheritance patterns and multifactorial inheritance. Some hereditary disorders that affect the eye have multiple genetic causes. The incidence of retinitis pigmentosa is about 1 in 3,000, much more common than would be expected from a disease caused by a single gene. Inheritance follows autosomal-dominant, autosomal-recessive and X-linked patterns. Although retinitis pigmentosa was thought to be a hereditary disease in all cases, a recent analysis of a large group of patients using segregation analysis, a complicated mathematical model, showed that some forms are not hereditary; the responsible environmental factors are not yet known.

The story of retinoblastoma has recently been unraveled. Strong evidence implicates a gene for this ocular malignancy on the short arm of chromosome 13 near the gene for esterase D, an enzyme that is unrelated to retinoblastoma. It is now believed that both the hereditary and the chromosomal forms of the disease are caused by an abnormality of the same gene. Neither the DNA sequence nor the biologic function of this oncogene has been identified.

The precedent for bringing a lawsuit for a wrongful birth has been set in the state of California by several cases that have been decided by the Supreme Court. Ophthalmologists and other physicians should consider the possibility of genetic factors in their visually handicapped patients; geneticists are well trained to relay information about hereditary disorders and congenital malformations without imposing value judgments.

J. Bronwyn Bateman, M.D.

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Laser Treatment for Glaucoma

The ophthalmic laser was one of the earliest clinical applications of laser technology to medicine. Treatment of ocular disease primarily involved laser therapy for diseases of the macula, retinal tears and diabetic retinopathy. More recently, the argon laser has become a significant aid in the surgical treatment of both open-angle and closed-angle glaucoma. By using the laser, the number of patients requiring a conventional glaucoma operation has been reduced along with the associated complications, prolonged hospital care and inconvenience to patients and physicians.

Argon laser trabeculoplasty is the procedure used for open-angle glaucoma. Currently, it is the primary procedure of choice when the intraocular pressure cannot be adequately controlled medically. By placing small laser burns in the trabecular meshwork of the anterior chamber, the outflow facility of the eye increases and the intraocular pressure decreases. The 50 micron-sized burns are not full thickness, but cause stretching of the adjacent trabecular meshwork and enlarge the outflow channels. The surgical procedure is done on an outpatient basis, requires only topical anesthesia and is associated with minimal patient discomfort. Long-term follow-up is not available as the procedure first became a clinical research tool in the middle and late 1970s; however, three-year follow-up studies show an average decrease in intraocular pressure of 6 to 8 mm of mercury.

The optimal number of burns, their exact placement and the extent of the angle area to be treated are issues still under investigation.

For surgical management of cases of narrow (occludable)anterior chamber and narrow-angle glaucoma, argon laser iridotomy has replaced surgical iridectomy in all but the most difficult cases. This procedure is also done on an outpatient basis with topical anesthesia and minimal discomfort. In laster iridotomy, light is absorbed by the melanin pigment in the iris. The heat generated from the laser burn produces a full thickness iris hole and allows aqueous humor to flow from the posterior to the anterior chamber of the eye. This relieves the pupillary block mechanism of narrow-angle glaucoma. After laser iridotomy the intraocular pressure is elevated temporarily from the dispersion of pigment into the anterior chamber. This elevation is usually mild and can be controlled medically. Some iris colors increase the difficulty of the procedure, particularly very light blue and very dark brown irides. Occasionally a full-thickness hole cannot be produced, requiring a repeat laser attempt or a conventional surgical iridectomy. Lens burn, mild iritis and corneal burns have been noted.

Argon laser trabeculoplasty and argon laser iridotomy are acceptable modes of surgical therapy, and have been valuable adjuncts in the clinical management of glaucoma.

E. Leigh Wilkinson, M.D.
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Corneal Preservation

The collection, evaluation and preservation of viable corneal tissue for purposes of transplantation are the major functions of a modern eye bank. Prospective donors are carefully screened by eye bank personnel for transmissible diseases or disqualifying ocular disease that would contraindicate their use as graft material. Tissue is then removed from a donor by enucleation of the whole globe or by excision of the cornea and a rim of sclera from the globe in situ within six hours after death.

Corneal tissue is evaluated by morphologic examination of the cornea with a slip-lamp biomicroscope or by using more recently developed specular microscopy for examination and counting of corneal endothelial cells.

Tissue preservation is necessary to allow for preparation of patients and transport of tissue and is accomplished by one of three methods: (1) moist-chamber storage of the whole globe, (2) intermediate cold storage in tissue culture medium and (3) long-term preservation in organ culture systems.

Corneas preserved as part of an intact globe in cold, moist-chamber storage must be used within 24 to 48 hours after death (short term). Storage of an excised cornea in modified tissue culture medium (McCarey-Kaufman [MK] medium) at 4 °C extends tissue viability to 96 hours postmortem (intermediate term). More recently developed preservation of the delicate corneal endothelium in organ culture at 37 °C has extended endothelial viability in storage to several weeks (long term). Most eye banks currently use intermediate-term preservation (MK medium).

Meticulous care to details of aseptic technique and preservation of endothelial integrity have enabled eye banks to provide excellent tissue to transplant surgeons and their patients. Medical standards for the qualifications of eye bank personnel, screening of appropriate donors, techniques of tissue handling and methods of corneal preservation have been determined by the Eye Bank Association of America.

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Extended-Wear Lenses and Corneal Infections

Extended-wear soft contact lenses have been approved for use in both myopic and hyperopic patients for several years. While some of the initial concerns involved the ability of the cornea to metabolically tolerate these lenses over longer periods, this has not proved to be of major consequence. Rather, more significant problems have occurred in two other areas—lens maintenance and infections. Some patients must remove their lenses to eliminate films and deposits. Unfortunately this is especially true in older patients who would benefit most from limited handling. While this problem provides a certain inconvenience, it is of no serious medical consequence.

Infection, however, may be the cause of permanent visual loss. It has been shown that merely having an extended-wear lens in place does not seem to change the normal bacterial flora of the eye. Nevertheless, corneal ulcers can and do occur, resulting in corneal scarring. Whereas these infections are uncommon, they occur when least expected and without warning. One would think that decreased handling would result in reduced incidences of infection, but this is apparently not the case. They are probably related to oxygen compromise. Continual administration of antibiotic drops is not justified, although hygiene is important to maintain. It is vital, however, that a red eye in a patient using extended-wear lenses be reported to that patient's ophthalmologist immediately.

Richard Elander, M.D.

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YAG Laser Posterior Capsulotomy

Cataract operations and intraocular lens implantation have changed dramatically in the past decade. Extracapsular sugical treatment in which the posterior capsule of the lens is preserved is popular because of the possible benefits of improved lens fixation and reduced risk of retinal detachment and cystoid macular edema. In 30% to 50% of cases, the posterior capsule opacifes in the years following a cataract operation. Until recently treatment of opacified capsules was limited to invasive procedures to open the membrane.

Working simultaneously and independently, Aron-Rosa of Paris and Frankhauser of Bern, Switzerland, developed short-pulse high-power neodymium-YAG (yttrium-aluminum-garnet) lasers for use in ophthalmology. These lasers use extremely high-power densities that cause optical breakdown, leading to a mechanical separation of tissue. These instruments were quickly adapted to the problem of an opaque posterior capsule and are now widely used for noninvasive laser procedures to open these membranes.

Laser operations for secondary capsulotomy have several advantages over invasive procedures. The laser procedure is totally noninvasive, eliminating the risk of infection. The opening in a capsule can be designed more precisely than a surgical capsulotomy. The treatment is painless and is done on an outpatient basis, reducing cost and patient discomfort. Complications have included a temporary increase in intraocular pressure after capsulotomy and damage to lens implants. Lens implant damage has had only minor effects on visual acuity and can be minimized with proper treatment technique and lens implant design. The increased intraocular pressure problem is currently being investigated.

Other uses of the YAG laser include iridotomy and vitreous strand cutting, which are promising applications but have not achieved the widespread acceptance of posterior capsulotomy. Posterior capsulotomy remains under the control of the Food and Drug Administration, with the YAG laser being an investigational device.

Confusion persists among lay persons and medical professionals concerning "laser cataract surgery." The YAG laser can open the opaque posterior capsule after a cataract operation, but no laser treatment can remove a cataract.

Thomas A. Hanscom, M.D,

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Macular Function Testing

In patients whose eyes have such dense cataracts that the retina cannot be seen, the functional state of the macula must be evaluated so as to provide the most accurate prognosis concerning postoperative visual acuity. Instruments recently developed to predict more accurately the visual outcome following a surgical procedure include the blue-field entoptoscope, interferometers that use either incandescent or laser light and the potential acuity meter.

The blue-field entoptoscope is a light projector into which a patient peers. The light is deep blue and of varying intensity. A patient with a normal macula will report briskly moving particles in a fairly regular pattern, evenly distributed over the entire field.

Interferometric fringe patterns are also used. They are generated from an incandescent light source or a helium-neon laser. Interference fringe patterns are produced that are projected on the retina as a series of parallel lines of varying coarseness. The finer the perceived fringe, the better the predicted visual acuity.

The potential acuity meter is the most recent arrival of these new instruments. This is an elegant Snellen's vision chart projector, which is attached to the slit lamp. By aiming it at the clearest portion of the cataract and asking the patient to search around for the clearest view, a formal vision chart can be clearly projected onto the macula.

In very dense cataracts the images to be seen with these instruments often cannot be perceived even with a normal macula, and their predictive value is much less accurate. In moderately dense cataracts a good preoperative measurement with any of the above instruments offers a greater assurance of good postoperative visual acuity.

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BEHIND THE FACE OF HYPERTENSION

New evidence for central control

Alzheimer's Disease: The Human Response

MARTHA O. ADAMS

For the victim, it is a steady progression into the hell of mindless confusion until at last there is not mind enough left to be confused .. a lonely wandering between life and death. Alzheimer's disease, like many other taboos, is coming out into the open air of public thought and concern. For the general public it is a matter of education. For the afflicted family it is a pilgrimage, often a nightmare. It can become a catalyst, if used as such, to developing character—sometimes gentle, sometimes violent, always ruthless. For the primary care giver it is a thief that steals the essence of a loving companionship and leaves in its place mental, physical and emotional exhaustion.

My mother is in the advanced stages of this disease. I have struggled along with the rest of the family to adjust to its demands. We have developed some helpful methods of living as normally as possible through trial and error; persistence; extraordinary discipline on my father's part regarding routine, diet, and exercise; continuous education; and now a local support group.

I am a member of ADRDA (Alzheimer's Disease and Related Disorders Association) a national organization which works with families of Alzheimer's sufferers. I have read widely on the subject, attended lectures by prominent physicians in the field[1] and as writer and educator, have tried to stay close to the situation at home giving much thought and effort to creative solutions to the enormous problems my parents are facing together.

As the progression of this disease is in stages, suggestions differ for each stage, although the movement from one into the other is very subtle.

Early Stages

It began eight years ago in the kitchen when Mother and I were preparing vegetables. We had just finished laughing over stories I had been telling about some of our daughter's dating experiences. Moments later Mother asked, "What has Laura been doing lately?" I was shocked and it showed. She knew immediately and quickly changed the subject.

Difficulty remembering and skillful concealing of forgetfulness marks the earliest stages.

Usual Family Response

Astonishment at such incidents of immediate memory loss is common. "I just *told* you that!" an angry retort born out of frustration often accompanies accusations of not concentrating. Such a response frightens the person into worrying that anything said will expose her/his forgetfulness and communication begins to diminish. In these early stages the afflicted is acutely aware of being confused. Also common is the avoidance of talking about this as a problem with anyone.

Helpful Family Response

Begin to become aware of the frequency of such incidents. Learn to empathize: "I notice you're really having some trouble remembering. Is it becoming a problem to you? Let's work together and see if we can come up with some helps with the forgetfulness."

Find a doctor who will deal with the problem seriously. Some will try to laugh it off as a problem we all face as we grow older. A thorough physical is in order. Take a record of all medications being used by the patient. List troublesome behavior; i.e. over dependency, poor hygiene or table manners, withdrawal, depression. There are numbers of treatable physical conditions which can cause similar symptoms.

Middle Stages

The disease is now beginning to be diagnosed at this stage.

It took us three years of periodic searching to find the family silver hidden in a lamp shade box in the attic. We knew then that we were battling an invisible, insidious enemy. The constant misplacing of things is enough in itself to drive entire families to distraction.

Although usually able to continue a fairly normal life for some time, some Alzheimer suffers become depressed or irritable, others remain outwardly cheerful. There will be gradual impairment of understanding,

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reasoning and ability to use good judgment. Some experience changes in personality. More often, however, lifelong personality patterns are increasingly exaggerated. Participation in decision making, treatment, and planning for the future should be encouraged. The ability to perform sequential tasks becomes severely impaired; i.e. planning and preparing meals, housekeeping, paying bills, financial planning, home repairs. A gradual loss of lifelong skills such as driving, keeping a check book and counting money come as blows to the afflicted and the care giver.

Usual Family Response

Adaptation to these losses differs in as many ways as there are families who suffer them. We went through all of the following: bewilderment at what was happening and what to do about it, focusing on the lost capacities, rage at time spent finding misplaced items, overwhelming grief and frustration at the enormity of the problem and the lack of workable solutions or hope for reprieve, insidious fear that "I may get it, too," overprotection of the afflicted to spare embarrassment, still not talking about the problem much with each other or with friends, depression on the part of the afflicted, the care giver and close family members, isolation as friends begin to avoid coming, confused feelings of hate and love for the afflicted which are the beginnings of separation, anger at being stuck with such an unrelenting burden, and guilt at having all these feelings about someone one loves.

Helpful Response by Family and Friends

Go at it with a team approach. Make it clear that it is "our" problem we face together. When Alzheimer's is finally diagnosed (and this may legitimately take a period of some months) begin to become educated about the disease. Read "The 36 Hour Day" by Nancy L. Mace and Peter V. Rabins, M.D. Other excellent books are now being published.[2] Remind yourself daily that many of the peculiar things the person says and does are out of his/her control. It is the result of damage within the brain.

Expect to feel grief and allow yourself to share it. Contact the Alzheimer's Disease and Related Disorders Association near you.[3] Become an informed supporter of the work they do. They will send you local information on ADRDA chapters. Look for other Alzheimer support groups by checking local hospitals, visiting nurse associations and public health departments. Talk about the problem with each other and those who also suffer as you do. This in itself will help alleviate many of the conflicting feelings of helplessness, hopelessness, guilt and anger and at the same time will help you be informed of the newest research and developing treatments.

Understand that your friends' seeming neglect is mostly from mistrust of their own sense of knowing how to respond to the afflicted and to you. Be specific with them about what they can do. In general, do anything with the afflicted either in the home or outside that frees the care giver to leave and do something she/he needs or wants to do, i.e. take her/him out for lunch, shopping, to visit an old friend, to a museum, the grocery store, post office, hair dresser or movie. Bring lunch in to sit with and visit the afflicted. Read to her. Listen to him read a simple story. Bring picture post cards or family pictures to look at.

Maintain as calm an environment as is possible. Don't argue with the afflicted person. Distract him/her by changing the subject or focus of attention. Establish a routine and stick to it. Strive for consistency in daily schedule and in manner of response, i.e. speak clearly, firmly stating the business at hand anticipating understanding and compliance. Be attentive to a balanced diet and regular exercise for both the afflicted and the care giver.

Be very intentional about keeping the person in touch with reality. There are a number of ways to do this. Put up a plastic coated message board in a conspicuous place. On it keep posted the day, month, year and any pertinent messages such as where you are going, when you will return and at what number you can be reached when you need to be away. If the person continues to repeat a question, write the answer on a 3x5 card and give it to him/her to carry in a pocket. Reminding him/her to read the card is easier than explaining repeatedly. Using the same card idea, write out the day's schedule or any sequence of events about which the person is troubled by forgetting. Don't affirm confusions; correct and reorient, reminding often of the date and time. Continue to encourage decision making and participation to the fullest extent possible in routine skills, tasks, and meaningful activities. Allow more time for everything.

Consider safety factors such as covering the stove top or locking doors if the person is prone to wander. Have the person wear a medical identification bracelet with name, address, phone number and "memory impaired" information. Respond to confusion with facts no matter how painful, but be quick to reward accomplishments with immediate praise.

Use this time to explore the person's memories of the past as these memories are heightened and often clear. Document family history by talking on a tape recorder together about pictures, old family pieces of furniture or china, important incidents and events in the person's past.

At this point, investigation of nursing homes, insurance and legal matters, and social services for in-home help is appropriate. Begin to be more conscious of needing to take care of yourself as the care giver. As the disease progresses, your time and energy become more acutely involved in caring for the other. Begin to plan for ways to best adjust to the increasing demands. This may involve relocating residency to be nearer younger family members, entering a retirement complex which has health care facilities, simplifying your living to smaller more easily manageable quarters such as a mobile home park, and/or beginning to hire help to come into your home. It is extremely important to remember that you are a person who still needs friends, love, food, rest and entertainment.

Advanced Stages

In addition to impairment of memory, visual perception, speaking, reading, writing and walking begin to be affected. Hallucinations may occur. A total lack of privacy is suffered by the care giver who is followed everywhere by the afflicted, even into the bathroom. Erratic sleep patterns and night wandering are common. Loss of bladder and bowel function, loss of speech and confinement to bed may be the results of the progression of brain deterioration which transpires before the ultimate loss of so many bodily functions, including the ability to communicate pain, that death occurs often brought on by infection resulting in pneumonia. Each individual walks this grim path in his or her own unique way suffering gradual mental and physical deterioration in a specifically unpredictable progression.

Usual Family Response

This is determined to a great extent by finances and how a family has dealt with the problem to this point. For adult children who are geographically removed and busy with their own lives there is often avoidance of responsibility and simultaneous feelings of guilt. The burden falls to the spouse and/or one adult child with intense (and often unspoken) resentment of the others who are not as involved. Feelings of despair and anger are common. "Why me?" Fatigue brings about a frustrated giving in to unreasonable demands by the afflicted thus rewarding unsatisfactory behavior. The care giver can become less and less able or willing to make major decisions and seek assistance.

There is a heightened sense of sadness and bidding farewell to a loved one who no longer resembles the person of the past. This is emotional work that has to be done.

Helpful Response

Communication among family members and close friends is most vital. Listen carefully for masked or outright cries for help from the primary care giver.

Speak clearly to the afflicted. State who you are, why you're here and what you've been doing to help. Give directions calmly, again, expecting compliance. Insist the person be involved in his/her own personal care. Remove inappropriate clothes from the closet. Choose clothes that are simple to put on and launder. Do things with, not to the afflicted. Learn to divert the person's attention to other things to avoid hostilities.

Try not to be over protective, focus on lost capabilities, give in to unreasonable demands, or reward unsatisfactory behavior. This is very difficult.

If nursing home care is financially possible and decided upon, try to accept the idea that you are only one and have done your best. You continue to do so by such placement of your loved one into the care of a team of professionals. Clergy and doctor can be extremely helpful in this decision process. Ideally, throughout the illness, the doctor has seen it as his/her job to make your life as bearable as possible. Visit the afflicted regularly if possible, keeping the above suggestions in mind.

This is the time when the spouse left alone at home needs the most help and support by family and friends. Visits, invitations and involvements outside the home become a life line to re-engagement with the living.

Millions of Americans scurry regularly to the newsstands, magazine racks, libraries, and T.V. schedules looking for help with this disease which is suffered by two or three million of us. Translated into world figures, the scope and cost in human suffering and dollars spent on nursing home care is staggering. Like cancer, few families are untouched. What we see is primarily despair. What we are missing is help with the human response which is all there is to help until medical research can define the cause and develop effective treatment or means of prevention.

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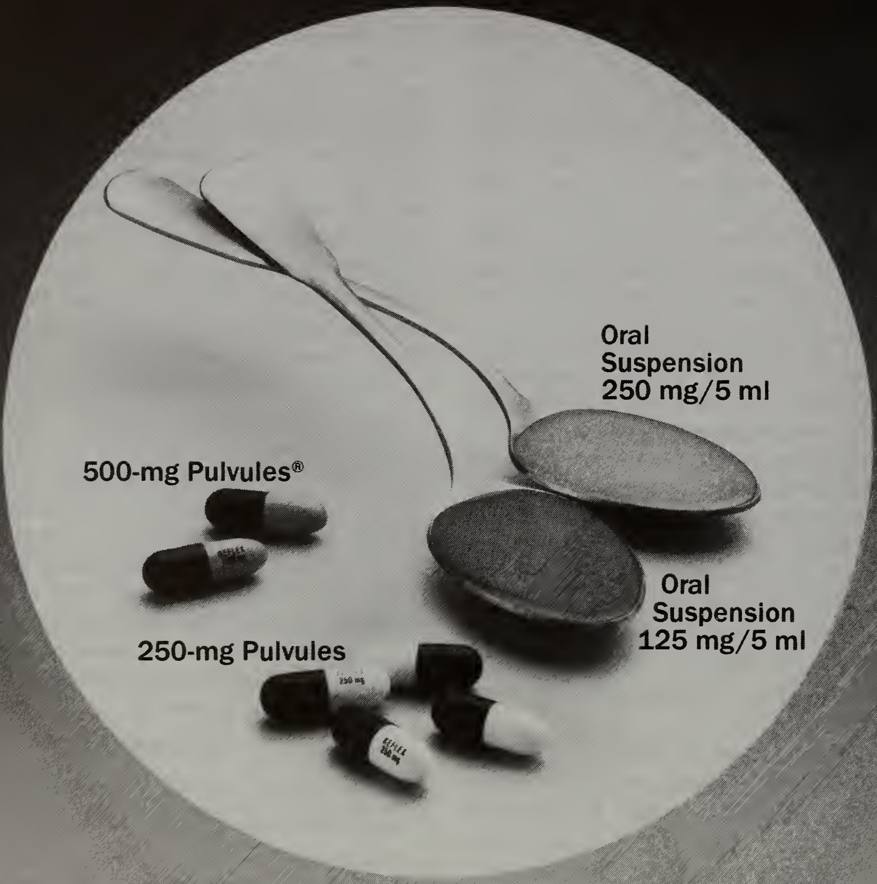

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Ethics Committees in Hospitals: Alternative Structures and Responsibilities

JOHN A. ROBERTSON, J.D.

Should hospitals create institutional ethics committees (IECs)—groups of persons that, on an optional or mandatory basis, advise, discuss, or consult with health care professionals, patients, and their families or representatives about ethical issues that arise in clinical care? If so, how should such committees be organized and how should they function?

The Origins of IECs

There is nothing novel about the use of committees for decision making in the practice of medicine. Hospital medical affairs traditionally have been governed by credentialing, tissue, mortality, pharmacy and therapeutics, records, and other committees. Committees dealing with professional ethics and discipline are an integral feature of medical society regulation of physicians.

Committees to consider ethical issues arising from or influencing clinical care date from the early 20th century. Sterilization legislation, a product of the eugenics movement, led, in the 1920s, to the creation of committees to regulate clinical decisions. Before an individual could be sterilized, an institutional committee of three or four professionals, usually physicians, first had to find the individual "feebleminded."[1] The nation's highly restrictive abortion policy of the 1950s and 1960s gave rise to therapeutic abortion committees that determined when abortions were medically justified.[2] Before 1973, when Medicare funding made renal dialysis available to all who needed it, committees played an important role in allocating scarce dialysis services for end-stage renal disease patients.[3] Professional standards review organizations (PSROs), legislated in 1972, form a national network of committees playing a regulatory role in the clinical setting.

The type of committee most closely related to the IEC, however, is the institutional review board (IRB), which institutions receiving federal research funds are required to establish. The IRB system was created when it became clear that medical researchers sometimes advanced their own interests at the expense of human study subjects. IRBs review research proposals involving human subjects and ensure that researchers are aware of applicable rules, such as those related to informed consent. Because they are the cornerstone of federal research policy, IRBs are a model with which many hospital administrators and physicians are familiar and to which they can look when forming an IEC.

The IEC, while similar in some ways to the other types of committees, is unique in that it goes beyond a few confined or specialized areas, such as research or abortion, to deal with the numerous and diverse ethical issues that arise in the care of critically and terminally ill patients.

The Rationale for IECs

In the late 1960s and early 1970s, health care professionals began to realize that their ability to extend the lives of critically and terminally ill patients with sophisticated new technology and methods of treatment had added social, ethical, and legal components to what once were almost exclusively medical decisions on death and dying. As the nonmedical, normative nature of some clinical decisions became clear, many in the health care community decided that the public should be involved in questions of prolonging or not prolonging life, and that legal rules specifying standards and the authority of various figures were needed.

The first mention of an IEC in a legal context appeared in the New Jersey Supreme Court's 1976 opinion in *In re* Quinlan. In appointing Karen Quinlan's father guardian and authorizing him to remove his daughter from a respirator, the court held that immunity from suit for such decisions would be provided if a hospital ethics committee reviewed and confirmed the prognosis.[4] Since 1976, ethics committees have been mentioned in a number

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This article is adapted from a presentation made by Mr. Robertson at the American Society of Law and Medicine conference on institutional ethics committees, held in Washington, DC on April 21-23, 1983.

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of other court cases.[5] In 1983, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research recommended that ethics committees function as part of an intrainstitutional review system for nontreatment decisions.[6] Ethics committees also have been suggested as an alternative to the hotline approach of the federal government's Baby Doe regulations.

Although, the *Quinlan* opinion supported the idea of using ethics committees in clinical medicine, it was, ironically, based on two faulty assumptions. First, the court referred to an "ethics committee" when the group it described might have been more accurately called a "prognosis confirmation committee," because it was charged with confirming a physician's judgment that a patient was irreversibly comatose.[6] Second, the court relied on a committee structure that it presumed existed in nearly every hospital, although then, as now, ethics committees existed in very few hospitals. Thus, rather than expanding the role of an existing mechanism for reviewing clinical decisions, the ethics committee concept of the New Jersey Supreme Court entailed creation of a new regulatory body.

The public also has pressed for more systematic review of ethical issues in medicine. Unfortunately, most health care providers are neither intellectually prepared to address these issues nor emotionally comfortable discussing them, even if they have had an undergraduate or professional school course in ethics. Resources short of a fullfledged IEC, such as a hospital ethicist, moral philosopher, or member of the clergy, can be helpful, but many problems require more wide-ranging discussion and a broader perspective than a single ethicist can provide. A committee, which is more representative of community values and of differing moral and professional perspectives, may be desirable.

There are several functions that an ethics committee can perform for an institution and for its physicians, staff, and patients. One function is to facilitate analytic moral inquiry by identifying conflicting interests, rights, and duties and aiding in the reconciliation of competing goals. A second closely related function is an educative one. Just as IRBs help educate investigators about ethical norms in research, IECs can help educate health care professionals about the moral issues and conflicts that arise in clinical practice and about acceptable ways to resolve them. They also can play an important role in developing hospital policy and guidelines on such issues as informed consent and do-not-resuscitate orders.

"Most health care providers are neither intellectually prepared to address [Ethical] issues nor emotionally comfortable discussing them --- A committee, which is more representative of community values and of differing moral and professional perspectives, may be desirable."

The third function is a supportive one. Decisions to terminate treatment often excite profound and complex emotions. An IEC can help physicians and nurses cope with the stress of ethical dilemmas by providing a forum where they can openly discuss their positions and by providing information, support, and some assurance that their actions are in line with community standards.

A fourth function that an IEC can perform is resolution of disputes among staff members and between staff, patients, and patients' families over nontreatment decisions. Because such disputes may produce acrimonious feelings, it is important to have an in-hospital forum for resolving them rather than having resolution occur by fiat of the most senior member of the medical team or by complaints to law enforcement officials. An open forum may prevent ethical disagreements from spilling over into the criminal justice system, as occurred in the *Edelin* case in Massachusetts, the Danville, Illinois, Siamese twins case, and the Kaiser-Permanente murder case in California.[8-10]

Finally, from a pragmatic standpoint, an IEC can help protect health care professionals, patients, patients' families, and institutions from lawsuits. At present, neither legislation nor court decisions require that hospitals create and operate IECs or that physicians consult them. However, in New Jersey, New York, and Washington, IEC review and approval of decisions to terminate life support for irreversibly comatose patients will provide immunity from civil and criminal liability. In other states, such as Massachusetts, where only a court can provide advance immunity from liability, resort to an IEC will show a health care professional's good faith and reasonableness and may give de facto immunity.[11-12] Even if the health care professional chooses not to follow the IEC's advice, he or she may still gain protection because the ultimate legal issue will be whether or not the professional acted reasonably in reaching the clinical decision, an issue not necessarily determined by the IEC's recommendations. Thus, the IEC can function as an ethical risk management team, protecting the institution and individual staff members as well as the patients and their families.

Optional-Optional Ethics Committees

A hospital, if it follows its designated governance procedures, has ample authority to create an ethics committee and to require that it be consulted and allowed to assume management of particular cases.[13] However, an ethics committee with a structure that gives health care providers the option of consulting it and also the option of following or disregarding the advice it offers may be preferable to a committee where consultation and adherence to the committee decision are required.

Operational and procedural issues. What is the jurisdiction and authority of an IEC, who will sit on it, and what procedures will it follow? The issue of jurisdiction is resolved by a decision to make the committee available to any physician or other designated staff member of the institution. The institution may also want to give patients, their families, or their representatives access to this forum. The issue of authority is moot for an optional-optional IEC because its purpose is to advise health care professionals and facilitate discussion of ethical issues, not to make binding decisions about case management.

The matter of committee composition requires discussion among the administrators, lawyers, and professional staff at the hospital establishing the IEC. The IRB model, a committee of at least five persons, one of whom is not from the institution, can be followed to form a base from which a hospital can build a workable IEC. [14] Obviously it is desirable to have someone with training in ethics on the committee. However, if an ethicist is not available, many IEC functions can still be performed by having members of the local clergy participate in case review.

The proceedings of an optional-optional IEC need not be formal; unlike IRBs, nothing written need be submitted and no records need be kept. Because the committee's sole purpose is to advise members of the health care team, there is no reason for its deliberations to be open to the public. Nor would an optional-optional IEC have to notify a patient, much less obtain the patient's permission, to consider his or her case, although it may be desirable to do so. The patient's explicit consent is not needed because the IEC proceeding is simply another form of consultation in which health care professionals engage for a patient's benefit and which is part of the implied contract between physician and patient.

Are IEC members vulnerable to law suits and are their records discoverable and admissible? While a grossly negligent review leading to patient or physician injury could, in theory, lead to IEC liability, most states have statutes giving hospital or medical staff review committees immunity from liability and making their records confidential. [15] If the applicable Minnesota statute is taken as a representative example, it is reasonably clear that, in Minnesota, an optional-optional IEC, functioning as an official hospital, or medical staff committee to review ethical issues that arise in medical practice, would be immune from liability and its records, if any have been kept, would be privileged against discovery and admission into evidence.

Objections to IECs

Some health care professionals will object to the formation of an IEC. A common concern is that an IEC will be prohibitively expensive to operate. However, because an IEC is not likely to be as active or elaborate as other hospital committees, such as IRBs or credentialing committees, cost should not be a major stumbling block.

A more serious problem is physician concern that an IEC will interfere with clinical judgment and the physician-patient relationship. The objection may have considerable validity in the context of mandatory case review by IECs with decision-making authority. Optional-optional IECs do not intrude on clinical judgment or the physician-patient relationship, however, because the decision to activate case review is entirely up to physicians. Even if nurses, patients, or patients' families can activate review, clinical judgment—though perforce exposed to other views—remains intact because the physician is not obligated to follow the committee's advice.

Indeed, the main problem with optional-optional IECs may well be underutilization. Data about existing ethics committees confirm this fear. Not only have physicians not favored creation of IECs, but where they exist, physicians have seldom used them. A survey for the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research found that no hospital with less than 200 beds had an IEC. [16] Only 1% of hospitals with over 200 beds had an IEC, and seven of those were in New Jersey where, after the *Quinlan* case, creation of prognosis confirmation committees (counted in the survey as IECs) was to be expected. When an IEC existed, it was used, on average, only once a year.

This low rate of utilization can be explained by the relative newness of IECs as a resource, health care professionals' ignorance of IEC goals and procedures, and the lack of incentive for IEC use. An additional factor that may impede development and use of even optional-optional IECs is physicians' desire for total independence and self-reliance in clinical decision making. A well-established physician from a prestigious medical school, in discussing the usefulness of an optional-optional IEC, remarked, "In 30 years of practice, I never had a case that I could not handle on my own." [17] This remark typifies an attitude that IECs must overcome if they are to fulfill their purpose.

Mandatory Review by IECs

Physician reluctance or outright refusal to use optional-optional IECs raises the question of whether ethics committee review of certain types of cases should be mandatory. If mandatory review is deemed necessary, should it be in a mandatory-optional or a mandatory-mandatory form?

In the mandatory-optional form, physicians would have to consult an IEC in certain cases but would not have to follow its advice. In the mandatory-mandatory form, physicians would be required to go to an IEC and to follow its recommendations. This form, in effect, transfers responsibility for management of certain cases away from the physician and to the IEC.

> *"The main problem with optional-optional IECs may well be underutilization. Data about existing ethics committees confirm this fear. Not only have physicians not favored creation of IECs, but where they exist, physicians have seldom used them."*

When should IEC review be mandatory? A general guideline would be to make review mandatory whenever there is a likelihood that a clinical decision will involve important nonmedical interests for the physician, family, or patient. The scope of mandatory review thus depends on a value judgment by a hospital's administrators, lawyers, and professional staff of the relative importance of the competing interests in certain types of cases and the likelihood that they may skew clinical judgment.

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research has recommended mandatory IEC review whenever parents and a physician are contemplating withholding treatment from a Down's syndrome or spina bifida child.[6] Mandatory review might also be considered when nutrition and fluids are withheld from incompetent, but nonterminally ill patients such as Karen Quinlan, or when bone marrow is obtained from minors or the retarded.

Will it be enough to require that physicians consult an IEC, leaving it up to them whether or not to follow the IEC's advice, or should both review and compliance with the IEC decision be required, as occurs with IRB review of human subject research?[13] Some clinical situations may be so fraught with ethical risks as to require that an IEC have final decision-making power.

At the present time, the most compelling case for such final decision-making power is made by the withholding of treatment from handicapped infants. It might be reasonable for a hospital to require that decisions to stop treatment of Down's syndrome and spina bifida children be reviewed by an IEC. Only if the IEC found that treatment was not in the child's interest would the parents' wishes to withhold treatment be followed. If the IEC disagreed and the parents continued to refuse consent for treatment, the hospital could then refer the case to child welfare authorities and the courts to gain legal authority to treat over the parents' wishes. Requiring IEC review of decisions to withhold treatment from handicapped infants also might defer further federal intervention in hospital affairs. Identifying cases such as these for which review should be mandatory and for which ultimate decision-making authority should rest with the IEC will be the most difficult task confronting the creators of an ethics committee.

Clearly, the review procedures for mandatory and optional IECs are quite different. When the mandatory-mandatory nature of review turns the IEC into a decision-making authority, the IEC has an obligation to involve the patient or the patient's representative in the decision-making process. It also has an obligation to open its proceedings to public scrutiny.

Comment

This brief survey of IECs suggests that health care institutions may want to consider forming a committee to be available for ethical consultation on an optional basis. It also suggests that, for a narrow category of cases, institutions may want to consider requiring some kind of mandatory, in-house ethics committee review. This new forum, based on the IRB model, can help health care professionals, patients, and patients' families wrestle with the ethical dilemmas that medical advances continue to create or exacerbate.

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Summer Hazards

CONNECTICUT POISON CONTROL CENTER

Exposure to poisonous plants, stinging insects, and venomous snakes are easily identified as the poisons of summer. Less obvious yet more frequently encountered are the potential hazards associated with warm-weather activities such as barbecues, sunbathing and picnics. Herein we present brief discussions of the "other" poisons of summer.

Insect Repellants

The acute ingestion of insect repellants generally does not result in severe signs and symptoms of toxicity. Most insect repellants contain the active ingredients -N, N-diethyl-m-toluamide (DEET) and/or dimethyl phthalate in liquid, aerosol, or cream form. The LD 50 (mice) for DEET is 2,400 mg/kg and that for dimethyl phtalate is 2,000 mg/kg. Since both chemicals cause a burning sensation of the lips, tongue, and mouth when tasted, the ingestion of large amounts is a rarity. (Dilution with fluids is the only treatment necessary for ingestion of amounts less than one ounce). The ingestion of more than this amount should be managed with emesis or lavage as well as activated charcoal and a cathartic. Massive ingestions have caused ataxia, CNS depression, and coma. Seizures are a possible reaction and should be treated with IV diazepam. Plasma levels of these ingredients are not clinically useful but heme, renal, and hepatic functions should be monitored.

Eye exposures may cause transient irritation. Thorough eye irrigation with normal saline should be performed and an ophthalmic consultation obtained if symptoms persist beyond irrigation.

Though intended for dermal use, these products may produce contact dermatitis in sensitive individuals. Washing with copious amounts of soapy water is sufficient for skin decontamination.

CITRONELLA OIL—Citronella oil is an older, less frequently encountered insect repellant that exhibits a pale to deep yellow color and highly characteristic odor. Ingestion of small amounts of the oil may cause GI upset. The low concentrations in the once popular "citronella candles" are usually insufficient for additional toxicity; oral dilution is all that is needed. Large amounts of the oil itself are said to irritate the entire urinary tract. Shock, cyanosis, and convulsions preceded death in a child who consumed an unknown quanity of a strong citronella solution. The lethal human dose is estimated at 0.5-5.0 Gm/kg.

PREPARED BY: Dorothy Kriss, R.N. (References available upon request).

Charcoal/Charcoal Lighter Fluid

CHARCOAL BRIQUETS—Charcoal briquets may contain coal, hardwood charcoal, limestone, cornstarch, and trace amounts of sodium nitrate. Some may contain paraffin or kerosene as an aid to ignition. The poor taste and granular consistency of charcoal briquets and pure charcoal tend to limit their ingestion to "taste" amounts in the curious toddler. Toxicity from nitrates (hypotension, tachycardia, methemoglobinemia) is highly unlikely due to the small concentrations present.

Recent questions have been raised concerning the safety of "pure" charcoal versus charcoal briquets. While briquets are certainly of a more artificial nature, the additives are burned off during the ignition process. All forms of charcoal should be allowed to reach full ignition (glowing coals) before food is cooked over the fire. The use of charcoal fires for indoor cooking and heating is strongly discouraged due to the large quantities of carbon monoxide produced by combustion.

CHARCOAL LIGHTER FLUID—These hydrocarbons are typically naphtha, kerosene, or mineral spirits. Due to their high volatility and low viscosity they possess strong aspiration potential when ingested and are both respiratory irritants and CNS depressants when inhaled.

DENNIS J. CREAN, R.N., Director, Connecticut Poison Control Center, The University of Connecticut Health Center, Farmington, CT.

The treatment of any petroleum distillate ingestion depends on the history of the exposure. Determination of the amount actually swallowed will be the basis for the decision to dilute the material in the stomach or to induce emesis or perform lavage depending on the amount taken and the presence of clinical signs: consult poison control when in doubt. The amount admitted to or observed, the presence of breath odor, and the comparison of before/after amounts in the container should all be considered. Fortunately the noxious taste and odor help to limit the amount that is accidently ingested. However the taste factor may actually induce the spasm or gag reflex that may lead to frank aspiration. All persons exhibiting coughing, choking, or dyspnea need evaluation in an emergency room.

In asymptomatic persons who have ingested less than 1 cc of charcoal lighter fluid per kilogram of body weight, dilution with milk or water and close observation are recommended. The hydrocarbon will likely pass through the GI tract causing burping, cramps, diarrhea or spontaneous emesis. Symptomatic care should be sufficient.

Persons who have ingested greater than 1 cc of lighter fluid per kilogram of body weight should be treated at the emergency room. The induction of emesis using Ipecac syrup is preferred to gastric lavage since emesis results in far less aspiration potential. Lavage should be held in reserve for persons who are comatose or without the gag reflex. Activated charcoal and a cathartic should follow evacuation of the stomach.

Aspiration carries high risk of chemical pneumonitis. Cases of suspected aspiration should receive baseline and sequential chest x-ray and arterial blood gas determinations. The use of antibiotics and steriods should be withheld until specific indications are present. If left untreated, the ingestion of lighter fluid may cause CNS depression or excitation, renal and hepatic impairment, or massive GI upset.

Eye and skin exposures require *thorough* irrigation with water.

PREPARED BY: Laura Kubeck, R.N. (References available upon request).

Sun Tanning Products

The wide and ever-growing variety of sun tanning products makes the specification of an exact product-name a helpful aid to treatment. The active ingredient in most tanning lotions, creams, butter, gels, and aerosols is PABA (p-amino-benzoic acid) in concentrations up to 5% (sun-protection factor 15). Additional constituents may include emollients, zinc oxide, local anesthetics, ethanol, and vegetable oils.

When ingested in small amounts, tanning products are likely to produce GI irritation; they should be diluted and managed symptomatically. Since the LD 50 of PABA is 0.5-5.0 Gm/kg, the ingestion of several ounces should be treated with emesis, activated charcoal, and a cathartic. Ultimately, PABA ingestion could result in methemoglobinemia, cardiac arrhythmia, and CNS depression if massive amounts are ingested and left untreated.

Many tanning agents that supply artificial color-enhancement in addition to sun blockers may contain menthyl salicylate (an ultraviolet sunlight blocker). In the body, menthyl salicylate is presumably hydrolyzed to menthol and salicyclic acid. Methyl salicylate is said to produce toxicity at a dose of 10 ml/kg as exhibited by GI irritation and the classic signs of salicylate toxicity (tinnitus, hyperventilation, pyrexia). Ingestion of massive amounts necessitates attempts to prevent absorption and to correct acid-base disturbance.

SUNBURN MEDICATIONS—As aerosols or lotions, sunburn relief medications provide local anesthesia and a cooling sensation to burned skin. Benzocaine (up to 4%), camphor, and/or menthol are usually present. All are potential methemoglobinemia inducers.

Ingestion of 5 cc of a 2% benzocaine solution has produced symptoms. Mild toxicity is characterized by GI upset, headaches, nausea, dizziness, and fatigue. More severe symptoms include cardiac arrhythmia, convulsions, hypotension, metabolic acidosis, and cyanosis.

Stomach evacuation with ipecac or lavage is recommended for ingestion of one ounce or more. Follow with activated charcoal and a cathartic. Diazepam (IV) may be necessary for seizure control as may sodium bicarbonate for correction of acidosis. Methylene blue and oxygen therapy are indicated for methemoglobinemia which should be monitored via serum levels.

Eye exposure should be subjected to copious irrigation with water or normal saline.

PREPARED BY: Janet Bouchard, R.N. (References available upon request).

First-Aid Supplies

CALAMINE—Calamine products remain a very common first aid preparation in many medicine cabinets and first aid kits. Calamine is a basic zinc carbonate 98%, colored with ferric oxide (0.5%). It is used as a mild astringent on the skin and is available in powder, cream, lotion, and ointment preparations.

Calamine lotions, commonly ingested by toddlers, are essentially non-toxic since they contain such low percentages of calamine. However, the ingestion of large quantities has produced vomiting and gastritis. The estimated oral lethal dose is 5-15 Gm/kg. Dilution with milk or water is all that is necessary for amounts consumed up to several ounces. Though spontaneous emesis is very likely when more than several ounces are ingested, it is better to induce emesis as early as possible rather than risking further absorption. Further treatment with activated charcoal may help to minimize further GI upset. In the eye, calamine may cause transient irritation which can be avoided by prompt and thorough flushing.

CALADRYL LOTION—is a topical antipruritic/antihistamine preparation that is considerably more toxic since it contains diphenhydramine hydrochloride (Benadryl) 10 mg/cc, camphor, and alcohol along with calamine. Estimates of the fatal dose for Benadryl range from 20 to 40 mg/kg. Individual variation is significant as evidenced in several case reports: 60 mg was fatal to a 2 year old, 700 mg was tolerated by a 3 year old, and 7.5 grams led to seizures, acidosis, hypotension, and death in a 14-year-old.

Caladryl also contains camphor (1 mg/cc) and ethanol (1%). The presence of camphor in any poison should alert the clinician to the possibility of CNS excitation with rapid onset.

Symptoms of caladryl ingestion include GI upset, headache, delirium, drowsiness, hyperactivity, rash, confusion, and flushing. Serious intoxication may lead to tachycardia, convulsions, dyspnea, fever, and coma. CNS excitation tends to predominate in children while excitation in adults is often preceeded by drowsiness and coma.

Taste amounts of caladryl should be diluted with milk or water and the patient closely observed. Full attempts to prevent absorption should be used for amounts larger than a taste (ipecac/lavage, activated charcoal, cathartics). Physostigmine may be helpful to reverse anticholinergic symptoms. Diazepam is the agent of choice for control of convulsions. The presence of camphor and alcohol make eye contact very painful: prompt irrigation with normal saline or water is usually sufficient.

TOPICAL STEROIDS—Over-the-counter steroid preparations for dermal application now have widespread distribution and usage. They are indicated for many types of dermatitis—(especially that caused by poison ivy or sumac) as well as for relief from insect bites and stings. Common brands include CortAid, Clini Cort, and Topi Cort. Hydrocortisone is usually present in the concentration of 0.5%. The emollient base may contain mineral oil, glycerin, lanolin, and petrolatum. Acute toxicity, even with ingestion of massive amounts of topical steroids, is highly unlikely due to the low product formulations. GI upset may be present due to the laxative effects of the emollients. Dilution with water or milk is the only treatment necessary.

MERCURACHROME—As a topical antiseptic for minor cuts and scratches, mercurachrome is usually found in 0.5-1.0 ounce bottles of 5% aqueous solution. The mercury content is closely bound and poorly absorbed. The fatal dose (rabbit LD 15 mg/kg) is 3-5 times that of the more soluble mercurial salts. Only slight GI upset has been reported upon ingestion. Dilution with fluids is recommended for ingestions up to 15 cc. Emesis should be induced for ingestions greater than this amount. Eye contamination with mercurachrome should be irrigated with normal saline or water for 10-15 minutes: no further treatment is necessary.

HYDROGEN PEROXIDE (H_2O_2)—In the experience of the CPC[c], H_2O_2 is ingested more frequently than any other first aid preparation. In 3% aqueous solutions H_2O_2 is an oxidant for use as a topical antiseptic. Because of its prevalence in medicine/first aid cabinets, it is commonly ingested by explorative toddlers. Adults using H_2O_2 as a mouthwash frequently swallow small amounts by accident.

In the bowel it is decomposed to water and oxygen. The most common symptom is persistent burping due to the large volume of gas (O_2) released. Dilution with water or milk will relieve irritation of the oral mucosa and GI tract. In the eye, 3% H_2O_2 causes immmediate but transient pain. Thorough eye irrigation will provide prompt relief.

NOTE: H_2O_2 in concentrations greater than 6% (as in hair bleach and laboratory products) should be regarded as potential *caustics* and dealt with accordingly.

PREPARED BY: Janet Bouchard, R.N. and Dennis Crean, R.N. (References available upon request).

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References:

1. Stone PH, Turi ZG, Muller JE: Efficacy of nifedipine therapy for refractory angina pectoris. *Am Heart J* 104:672-681, September 1982.
2. Antman E, Muller J, Goldberg S, et al: Nifedipine therapy for coronary-artery spasm: Experience in 127 patients. *N Engl J Med* 302:1269-1273, June 5, 1980.

BRIEF SUMMARY
PROCARDIA® (nifedipine) **CAPSULES** For Oral Use

INDICATIONS AND USAGE: I. Vasospastic Angina: PROCARDIA (nifedipine) is indicated for the management of vasospastic angina confirmed by any of the following criteria 1) classical pattern of angina at rest accompanied by ST segment elevation, 2) angina or coronary artery spasm provoked by ergonovine, or 3) angiographically demonstrated coronary artery spasm. In those patients who have had angiography, the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina, provided that the above criteria are satisfied. PROCARDIA may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed, e.g., where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm, or when angina is refractory to nitrates and or adequate doses of beta blockers

II. Chronic Stable Angina (Classical Effort-Associated Angina): PROCARDIA is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and or organic nitrates or who cannot tolerate those agents.

In chronic stable angina (effort-associated angina) PROGARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance but confirmation of sustained effectiveness and evaluation of long-term safety in those patients are incomplete

Controlled studies in small numbers of patients suggest concomitant use of PROCARDIA and beta blocking agents may be beneficial in patients with chronic stable angina, but available information is not sufficient to predict with confidence the effects of concurrent treatment, especially in patients with compromised left ventricular function or cardiac conduction abnormalities When introducing such concomitant therapy, care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs (See Warnings)

CONTRAINDICATIONS: Known hypersensitivity reaction to PROCARDIA

WARNINGS: Excessive Hypotension: Although in most patients, the hypotensive effect of PROCARDIA is modest and well tolerated, occasional patients have had excessive and poorly tolerated hypotension These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment, and may be more likely in patients on concomitant beta blockers

Severe hypotension and or increased fluid volume requirements have been reported in patients receiving PROCARDIA together with a beta blocking agent who underwent coronary artery bypass surgery using high dose fentanyl anesthesia The interaction with high dose fentanyl appears to be due to the combination of PROCARDIA and a beta blocker, but the possibility that it may occur with PROCARDIA alone, with low doses of fentanyl, in other surgical procedures, or with other narcotic analgesics cannot be ruled out In PROCARDIA treated patients where surgery using high dose fentanyl anesthesia is contemplated, the physician should be aware of these potential problems and, if the patient's condition permits, sufficient time (at least 36 hours) should be allowed for PROCARDIA to be washed out of the body prior to surgery

Increased Angina: Occasional patients have developed well documented increased frequency, duration or severity of angina on starting PROCARDIA or at the time of dosage increases The mechanism of this response is not established but could result from decreased coronary perfusion associated with decreased diastolic pressure with increased heart rate, or from increased demand resulting from increased heart rate alone

Beta Blocker Withdrawal: Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina, probably related to increased sensitivity to catecholamines. Initiation of PROCARDIA treatment will not prevent this occurrence and might be expected to exacerbate it by provoking reflex catecholamine release. There have been occasional reports of increased angina in a setting of beta blocker withdrawal and PROCARDIA initiation. It is important to taper beta blockers if possible, rather than stopping them abruptly before beginning PROCARDIA

Congestive Heart Failure: Rarely, patients, usually receiving a beta blocker, have developed heart failure after beginning PROCARDIA Patients with tight aortic stenosis may be at greater risk for such an event

PRECAUTIONS: General: Hypotension: Because PROCARDIA decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of PROCARDIA is suggested Close observation is especially recommended for patients already taking medications that are known to lower blood pressure. (See Warnings.)

Peripheral edema: Mild to moderate peripheral edema, typically associated with arterial vasodilation and not due to left ventricular dysfunction, occurs in about one in ten patients treated with PROCARDIA This edema occurs primarily in the lower extremities and usually responds to diuretic therapy With patients whose angina is complicated by congestive heart failure, care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

Drug interactions: Beta-adrenergic blocking agents (See Indications and Warnings.) Experience in over 1400 patients in a non-comparative clinical trial has shown that concomitant administration of PROCARDIA and beta-blocking agents is usually well tolerated, but there have been occasional literature reports suggesting that the combination may increase the likelihood of congestive heart failure, severe hypotension or exacerbation of angina.

Long-acting nitrates: PROCARDIA may be safely co-administered with nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

Digitalis: Administration of PROCARDIA with digoxin increased digoxin levels in nine of twelve normal volunteers The average increase was 45%. Another investigator found no increase in digoxin levels in thirteen patients with coronary artery disease. In an uncontrolled study of over two hundred patients with congestive heart failure during which digoxin blood levels were not measured, digitalis toxicity was not observed Since there have been isolated reports of patients with elevated digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing PROCARDIA to avoid possible over- or under-digitalization.

Carcinogenesis, mutagenesis, impairment of fertility: When given to rats prior to mating, nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose.

Pregnancy: Category C. Please see full prescribing information with reference to teratogenicity in rats, embryotoxicity in rats, mice and rabbits, and abnormalities in monkeys.

ADVERSE REACTIONS: The most common adverse events include dizziness or light-headedness, peripheral edema, nausea, weakness, headache and flushing each occurring in about 10% of patients, transient hypotension in about 5%, palpitation in about 2% and syncope in about 0.5% Syncopal episodes did not recur with reduction in the dose of PROCARDIA or concomitant antianginal medication Additionally, the following have been reported: muscle cramps, nervousness, dyspnea, nasal and chest congestion, diarrhea, constipation, inflammation, joint stiffness, shakiness, sleep disturbances, blurred vision, difficulties in balance, dermatitis, pruritus, urticaria, fever, sweating, chills, and sexual difficulties. Very rarely, introduction of PROCARDIA therapy was associated with an increase in anginal pain, possibly due to associated hypotension.

In addition, more serious adverse events were observed, not readily distinguishable from the natural history of the disease in these patients. It remains possible, however, that some or many of these events were drug related. Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2%. Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0.5% of patients.

Laboratory Tests: Rare, mild to moderate, transient elevations of enzymes such as alkaline phosphatase, CPK, LDH, SGOT, and SGPT have been noted, and a single incident of significantly elevated transaminases and alkaline phosphatase was seen in a patient with a history of gall bladder disease after about eleven months of nifedipine therapy. The relationship to PROCARDIA therapy is uncertain. These laboratory abnormalities have rarely been associated with clinical symptoms Cholestasis, possibly due to PROCARDIA therapy, has been reported twice in the extensive world literature

HOW SUPPLIED: Each orange, soft gelatin PROCARDIA CAPSULE contains 10 mg of nifedipine PROCARDIA CAPSULES are supplied in bottles of 100 (NDC 0069-2600-66), 300 (NDC 0069-2600-72), and unit dose (10x10) (NDC 0069-2600-41). The capsules should be protected from light and moisture and stored at controlled room temperature 59° to 77°F (15° to 25°C) in the manufacturer's original container.

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Month In Washington

Pro Bids Rejected For Many States

Operation of a new Medicare review system has suffered yet another delay in 15 states where all the bids for the peer review organization (PRO) contracts have been rejected as "technically unacceptable."

The rejected states have about 40% of all Medicare hospitalizations. New bidders there, along with the 18 rejected organizations, now have until July 5 to submit proposals. The rejected organizations met with Health Care Financing Administration officials May 30 and 31 to learn the specific deficiencies in their bids.

In two states—California and Michigan—multiple bids were submitted and rejected, according to HCFA spokesmen. In the other 13 states, only one bid was submitted. They are: Alaska, Connecticut, Hawaii, Idaho, Illinois, Maine, Ohio, Oklahoma, Pennsylvania, Texas, Vermont, Virginia and Washington.

Bidding for 47 PRO areas closed April 27 and HCFA officials say they did receive at least one bid from each of these areas. Bid requests were issued later and remain open until June 12 for three territories and for four states (Massachusetts, Maryland, New Jersey and New York) with Medicare waivers. With the bid rejections in 15 areas, the bidding is now completed in 32 states and open in 19 states and the territories.

In issuing the notice of reopened bids, HCFA noted that if it finds "no proposal acceptable" in the 15 areas, it will be "required to award a contract to a payer organization for that area." Officials in charge of implementing PROs say if it becomes necessary to use fiscal intermediaries for review, the bids will not be reopened. Rather the new duties will simply be added to existing intermediary contracts.

These officials added, however, that they "still feel very strongly that PROs should be run by physician-sponsored organizations" and are "giving the physician community every opportunity to participate."

Observers say, however, that the HCFA staff had hoped for greater competition for the PRO contracts and now wants to encourage competition from stronger out-of-state bidders for contracts in the 15 states.

Inadequacies in the 18 rejected bids reportedly fell into three categories: the contractual arrangements with subcontractors were either inadequate or involved too many subcontractors; the data base used by the bidder was seen as inappropriate; or the objective setting was ruled deficient.

Following the HCFA debriefing, AMPRA will sponsor a meeting at which the South Carolina and Wisconsin PSROs, which reportedly submitted the strongest PRO bids, will discuss their techniques. The AMA has also offered its assistance to the organizations that are resubmitting proposals. Most of the organizations say they will definitely bid again though some are not certain.

* * * *

Redefining Physician For the Government

An AMA-backed bill regarding the definition of physician under Medicare law has been introduced by Mississippi Democrat Wayne Dowdy.

The definition, used to delineate the types of practitioners and services Medicare pays for, has been applied in other contexts as well—including Medicare's proposed conditions of participation for hospitals.

Through the years, as Congress expanded Medicare benefits by broadening the physician definition, the definition has grown to include dentists, podiatrists, chiropractors, and optometrists, in addition to doctors of medicine and osteopathy. Under Rep. Dowdy's bill, only doctors of medicine and osteopathy would be defined as physicians. Medicare coverage for the services of the other practitioners would be unchanged, but these practitioners would be defined separately. Dentists would be defined as dentists; podiatrists, chiropractors and optometrists as "independently licensed health care practitioners."

* * * *

Shorter Stays Under DRGs?

Medicare's new diagnosis related groups (DRGs) payments are having the desired effect of reducing hospital lengths of stay without the unwanted side effect of increasing admissions, federal officials are reporting.

Data on the impact of the DRG program to date were presented to the Healthcare Financial Management As-

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Prepared by the Washington, D.C. Office of the American Medical Association

sociation May 5 by James Scott, Acting Deputy Administrator of the Health Care Financing Administration.

As of March 31, 43% of all hospitals were under DRGs for Medicare patients. The most prevalent DRG was 127 for heart failure and shock; the second most prevalent was DRG 39 for lens procedures.

Between October 1, 1983, (when DRGs were implemented in the first hospitals) and March 31, 1984, the average length of stay for Medicare patients billed under DRGs was 7.2 days. This compared with 9.1 days for non-DRG bills and 9.4 days in the same period a year earlier, Scott said.

The 7.2 day average may rise somewhat, however, because bills for complicated, long stays may only now be filtering in for payment and because many of the hospitals first affected by DRGs were in the south, where length of stay tends to be shorter than in the northeast.

In the first five months of fiscal 1984, an estimated 4.826 million Medicare patients were admitted to hospitals as compared to 4.792 million in the same period in 1983, Scott advised. When adjusted for leap year, this is a 0% increase in a year when admissions were projected to increase by 3.4%, he added, "so it is safe to conclude" that hospitals are not "jerking every third senior citizen they see on a street corner off to the hospital to maximize DRG payments."

* * * *

Stopping The 'Hoppers'

Physicians and other practitioners who lose their license in one state should not be permitted to hop from state to state, continuing to treat patients and collecting from Medicare and Medicaid in the process: That was the general agreement among physicians, federal officials and congressmen reacting to a General Accounting Office study that recommends tightening Medicare and Medicaid laws to permit the exclusion from the two programs of any practitioner whose license has been removed by a state licensing board.

GAO reviewed the proposal at a May hearing of the Senate Special Committee on Aging where all witnesses—including the Inspector General of the Department of Health and Human Services and a representative of the American Medical Association—supported the proposal's concept.

HHS Inspector General Richard Kusserow said his office is drawing up legislation to expand HHS' authority against sanctioned providers. AMA Board of Trustees Member John J. Ring, MD, reported that the AMA is expanding its dissemination to medical licensure boards of license revocation notices received for the AMA Physician Masterfile.

Others suggested remedies such as requiring states to report disciplinary actions to a national clearinghouse or denying controlled substances permits to physicians who are disciplined by licensure boards or who leave a jurisdiction while an investigation is pending.

The GAO based its recommendation on a study that traced health practitioners whose licenses were revoked in Michigan, Pennsylvania or Ohio between 1977 and 1982. Of the 328 sanctioned practitioners, (which included osteopaths, pharmacists, podiatrists, chiropractors, and dentists in addition to 144 physicians), 58% had lost their license due to quality of care problems such as malpractice, alcohol and drug abuse or immoral conduct. Twenty-three percent involved drug law violations.

A little more than a third of the practitioners held a license in at least one other state and 39 of these (including 24 physicians) enrolled in Medicare and Medicaid in another state.

* * * *

OMB vs HCFA: Battle Lines Drawn

A long-brewing battle between the Health Care Financing Administration and the Office of Management and Budget has prompted HCFA head Carolyne Davis to charge that OMB is "unsurping" her agency's authority over Medicare waivers and demonstrations.

The waivers and demonstrations permit Medicare to participate in state hospital rate-setting programs and other payment experiments. Medicare law gives authority to grant waivers to the Department of Health and Human Services where it is Davis' agency which makes the initial decision to award or deny a waiver.

For the past two years, however, OMB has used various tactics—including denial of the necessary forms for evaluating demonstrations—to hold up demonstrations. Since January, the Budget Office has required HCFA to submit for its approval any waiver applications involving more than $1 million a year.

HCFA protests resulted in an interim agreement in which OMB has 30 days to reach a decision on Medicaid research waivers, 10 days for policy waivers such as home and community based services, and 90 days for program waivers. Davis regards the OMB role as "fundamentally inappropriate," however, and in a memo to OMB early in May she accused the Budget Office of "usurption of HCFA's role."

The most obvious casulty to date has been a HCFA-approved experiment with social HMOs that OMB has held up with various demands for analysis. Still to come is the major battle involving waivers from Medicare's new prospective pricing system for state rate-setting programs. The PPS law requires HHS to exempt from the federal plan state programs that meet certain criteria, including the expectation that they will not cost more than the federal system.

Regulations to implement the PPS waivers have not yet been issues, however, despite repeated Congressional inquiries. Critics charge that the waiver authority is being held hostage in the battle between HCFA and OMB, and they claim that the Administration wants to deny PPS waivers to any states other than the four that already have them.

* * * *

Medicare Budget Bills Ready for Conference

Senate approval of a deficit reduction bill and a fiscal 1985 budget resolution in May have cleared the way for a House-Senate conference and final action on the measures.

Among the provisions to be taken up in conference is a Senate-endorsed physician fee freeze. The proposal would freeze Medicare's customary and prevailing fee limits for all physicians for one year. Prevailing fee limits would remain frozen for a second year for those physicians who don't agree to take all claims on assignment.

The final Senate measure claims Medicare savings of $8.2 billion over the next four years. In addition to the fee freeze, calculated to save $1.5 billion over four years, the measure would increase Part B premiums to save around $2 billion and curtail Medicare hospital payments to save $1 billion.

In the House bill, Medicare savings would be $833 million over the next three years. The House rejected a freeze and mandatory assignment on physician services to hospital inpatients. The House measure also does not include the continued freeze on prevailing fees for physicians who don't take assignments, reduced payments to hospital or increased beneficiary cost-sharing.

Both the House and Senate measures set up fee schedules for payments to clinical labs and call for a study of pacemaker reimbursement. The House plan would move up to July 1985 the date by which the Department of Health and Human Services must report on the "advisability and feasibility" of a diagnosis related group payment system for physicians.

* * * *

Medicare Goes HMO

Nearly two years after enactment of a law setting up a prospective payment option for Medicare HMO enrollees, the regulations to implement the law have been released by the Department of Health and Human Services. The new plan will cost the federal government nearly $100 million in its early years but long-range savings are expected.

The proposed regulations, which reportedly were delayed due to Office of Management and Budget cost concerns, were outlined at an HHS press conference May 22 and will be issued in final form this fall.

Under the proposal, HMOs, preferred provider organizations (PPOs), and other alternative delivery arrangements would have the option to continue under the cost-based arrangements most HMOs now have with Medicare; or they could move to a prospectively determined, capitated payment.

Under prospective payment, Medicare would pay the HMO up to 95% of the adjusted average per capita cost for Medicare beneficiaries in the fee-for-service system. The new plans are expected to reduce or eliminate Medicare's current cost-sharing. Beneficiaries would continue to pay Medicare's monthly Part B premium, now at $14.60 a month, however, and could be charged a new monthly HMO premium as well. That premium is expected to vary from about $20 to $50 a month.

About 775,000 or 2.5% of all Medicare beneficiaries are now enrolled in HMOs. Most of these are in 21 demonstration plans where reimbursement is similar to that in the new regulations.

HHS Secretary Margaret Heckler predicted that another 600,000 Medicare beneficiaries would enroll in HMOs within the next three or four years. She said the new payment arrangement will "mean more complete medical coverage with lower out-of-pocket costs" for beneficiaries and "long-term savings for the Medicare program" as well. She acknowledged, however, that the plan is expected to cost Medicare about $30 million in its first year of operation and $65 million in the second. Indeterminate savings are anticipated in the third year of the plan.

* * * *

Senate Gets Malpractice Bill

A medical malpractice bill introduced earlier this spring by Reps. Richard Gephardt (D-MO) and Henson Moore (R-LA) now has a Senate sponsor.

Minnesota Republican David Durenberger introduced the measure in the Senate on May 17. Called the Alternative Medical Liability Act of 1984, the bill would apply the no-fault concept to medical liability. It would apply only to patients whose care was paid for by the federal government though states would be encouraged to expand it to other citizens.

In introductory remarks, Durenberger said that while he does "not agree with all the provisions" in the bill, he does see it as "an important focus for national discussion" of the malpractice issue.

* * * *

Candidates' Outlook on Medicare

The major health policy difference between the two front-running Democratic Presidential contenders lies in their attitude toward preventive care, the candidates' health policy advisers agree.

Colorado Senator Gary Hart's policy would rely much more heavily on enhanced prevention measures to control health costs than would former Vice President Walter Mondale.

Both men, however, support a nationally-mandated, state-run health care cost containment program that would control hospital and physician charges for all hospital inpatients. Though details of the proposals may vary, both proposals are admittedly similar to legislation introduced by Sen. Edward Kennedy (D-MA) and Rep. Richard Gephardt (D-MO).

The candidates' views were outlined at a May meeting of the Healthcare Financing Management Association. Yale Professor Theodore Marmor, PhD, discussed Mondale's views. Hart's positions were detailed by Andrew Dunham, PhD. White House adviser Jack Svahn, who had been scheduled to present President Reagan's views, withdrew from the program.

* * * *

Government Loses Baby Doe

The government's controversial Baby Doe regulations, challenged by the AMA, have once again been struck down by the courts.

In his May 23 order, Judge Charles L. Brieant of the U.S. District Court for the Southern District of New York called the regulations "invalid, unlawful, and without statutory authority."

He based his ruling on a May 2 decision against the government in the case *United States* vs. *University Hospital* (Baby Jane Doe), which limited the statutory authority of Section 504 of the Rehabilitation Act. Section 504—the government's anti-discrimination law—was the legal backbone of the Baby Doe regulations.

The government had contended that Section 504 applied whenever an infant's handicap could influence medical decision-making. However, the court's earlier ruling stressed that Section 504 was designed to apply to issues of education, employment, and transportation.

"The AMA is elated with the ruling invalidating the final Baby Doe regulations. This ruling affirms that the federal government does not belong in cases involving the medical treatment of several handicapped newborns," according to a joint statement issues by Frank J. Jirka, Jr., MD, President of the AMA, and John J. Coury, Jr., MD, Chairman of the AMA Board of Trustees.

The AMA—joined in its suit by the American Hospital Association, the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, the Hospital Association of New York State, and the Association of American Medical Colleges—argued that the regulation exceeded the authority of Section 504.

* * * *

Surgeon General's Report on Smoking

Physicians can play an important role in reducing chronic lung disease which claims 50,000 lives each year from cigarette smoking, stresses the 1984 Surgeon General's Report on Smoking released in May.

Cigarette smoking causes 80-90% of all cases of chronic obstructive lung disease. In many studies, heavy smokers experienced 30 times the chronic lung disease mortality rate of non-smokers, said Surgeon General C. Everett Koop, MD, in a Washington press conference.

For the first time, the report describes the actual mechanism of disease: the inflammatory response to smoke produces high levels of elastase, an enzyme that degrades lung tissue; at the same time, smoke inactivates alphal-antiprotease, the protein that blocks elastase activity. Excess elastase can lead to diseases such as emphysema, according to the report.

It also underlines the need for physicians to promote quitting. "I am happy to report that we physicians have for the most part abandoned cigarette smoking; only 10% of us still smoke, compared to more than half of all physicians and surgeons just a few years ago," said Dr. Koop.

Just days prior to the report, Dr. Koop called for a smoke free society by year 2000, echoing AMA's 1983 policy statement.

* * * *

New Cigarette Labels

After months of negotiating between health and tobacco groups, Congress is on the verge of approving explicit warning label legislation that stresses the specific risks of cigarette smoking.

If approved in June as expected, cigarette packages would contain a different warning every three months:

- "Smoking causes lung cancer, heart disease, emphysema, and may complicate pregnancy,"
- "Smoking by pregnant women may result in fetal injury, premature birth, and low birth weight infants," and
- "Cigarette smoke contains carbon monoxide."

The new labels would be printed in a heavily bordered rectangle 50% larger than the current label. Similar warnings would be used in cigarette advertisements on billboards.

* * * *

'Deadly Dozen' Targeted in Congressional Races

An anti-abortion political action campaign announced in May its "hit list" of the twelve members of Congress it plans to attack in November's election.

The Congressional "Deadly Dozen" were chosen for their positions on abortion funding, fetal research, the confirmation of Surgeon General C. Everett Koop, Planned Parenthood, and the Equal Rights Amendment.

The votes of the targeted members have "helped to kill more than 17 million innocent pre-born children," said Rick Woodrow, Executive Director of the Life Amendment Political Action Committee (LAPAC).

The list includes Sens. Carl Levin (D-MI), Max Baucus (D-MT), Joseph Biden (D-DE), and Reps. Ike Andrews (D-NC), Peter Kostmayer (D-PA), Bob Carr (D-MI), Jerry Patterson (D-CA), Ronald Dellums (D-CA), Sherwood Boehlert (R-NY), Bob Edgar (D-PA), Clarence Long (D-MD), and Jim Jones (D-OK).

LAPAC plans to spend roughly $50,000 to unseat each candidate, advertising his pro-abortion voting record on television, radio and in newspapers.

* * * *

House Committee Approves New Organ Bill

On May 1, the House Energy and Commerce Committee passed a bill which would authorize $40 million over four years for grants to agencies that arrange for organ donations, and $30 million over two years to provide drugs needed by organ recipients. It also sets up a national transplantation network for matching organs to needy patients.

The House bill, HR-5580, does not include the controversial provisions listed in an earlier version, HR-4080, which permitted Medicare to limit coverage for all procedures—not just transplants—to selected patients, practitioners, and institutions.

* * * *

FDA Commissioner Selected

Frank E. Young, MD, Dean and Vice President of Health Affairs at the University of Rochester School of Medicine & Dentistry has been selected as the new Commissioner of the Food and Drug Administration.

A microbiologist, Dr. Young has devoted several years to the study of genetic cloning and mapping of bacteria. Most recently, he published papers on the cloning of a *Streptomyces* neomycin-resistant gene into *E. coli,* cloning of a gonorrhea plasmid into *E. coli,* and cloning of an *E. coli* gene into *Bacillus subtilis.*

Dr. Young will begin his appointment sometime after July. He is a member of the American Medical Association, the American Association of Medical Colleges, the American Association of Pathologists, and the American Society of Microbiologists.

Rx-To-Consumer Advertising Study Done

The Food and Drug Administration in May completed a study that measured recall, knowledge, and attitudes of roughly 1500 consumers about prescription drugs. The agency is now preparing a regulation that could permit limited prescription drug advertising by drug companies aimed directly at consumers.

* * * *

Video Terminals No Hazard, Physicians Tell Congress

Video display terminals (VDTs) pose no serious hazard to vision or pregnancy, physicians told members of a subcommittee of the House Education and Labor Committee during investigative hearings in May.

Since the early 1970s, when the use of VDTs became widespread, there have been reports of health effects produced by radiation emission. The most serious complaints focused on cataracts, miscarriages and birth defects.

The level of radiation emitted from VDTs is insufficient to cause spontaneous abortions or birth defects, said Marcus B. Bond, MD, of the American College of Obstetricians and Gynecologists (ACOG).

Both groups ACOG and the American Academy of Ophthalmology agreed that fatigue and physical discomfort may result from VDT use. Improper illumination, glare, a poorly designed workstation, and other stress factors should be changed to improve the working environment, they said.

* * * *

Vaccine Compensation Bill Heard

When an individual is vaccinated, society is protected from disease. It is only fair for society to protect the individual from the risks of vaccination, say supporters of the newly proposed National Childhood Vaccine-Injury Compensation Act.

"Large scale participation in the immunization program is essential for its success. Thus, there should be a public commitment to assure some form of compensation to those unavoidably injured," said sponsor Sen. Paula Hawkins (R-FL) in May hearings on the new bill before the Senate Committee on Labor and Human Resources.

The bill should ease the concerns of both parents and vaccine manufacturers, said Sen. Hawkins. By promising reimbursement for the medical expenses that result from adverse reactions, it may restore public confidence in the nation's vaccination program. By assuming liability for these adverse effects, it may encourage drug companies to stay in the vaccine business.

Choosing a Partner Without Trauma

DOROTHY R. SWEENEY, LEIF C. BECK, LL.B., CPBC AND
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The thought of recruiting a physician for a practice can be an unsettling and traumatic experience as a solo practitioner or a small group goes about the time consuming process. So much is at stake, both professionally and personally, that even the most efficient and knowledgeable doctor is often afraid to take the step.

Solo practitioners and members of small groups only occasionally in their lifetimes recruit and hire physicians to join them in practice. Selecting a physician to become one's "partner" therefore ranks among the most important decisions a senior doctor makes during a practice lifetime. The costs of an unfortunate choice, whether it fails because of clinical shortcomings or personality concerns, will be almost beyond measure. Unsatisfactory patient care may be perceived by the senior doctor(s); patient relations may be damaged and/or referring doctors may become dissatisfied. Just as devastating, the emotional strain of a poor peer relationship may take its toll on the senior physician, his or her family and the staff. Often this emotional strain causes the most damage.

On the other hand, a good choice is like manna from heaven. The practice adds a new and highly qualified member to provide increasingly fine care to its patients and the community. The existing doctor's or doctors' workloads and time demands might be reduced by the sharing of practice burdens without fear of poor results. Inter-doctor relations may be fostered by addition of a peer with whom to consult on the same wave length. Another highly skilled team member will increase or at least help the practice maintain its per-doctor income base. Personally as the relationship builds on confidence and trust, there becomes an added dimension that will serve both parties well in the future.

With both so much to lose and so much to gain, we wonder why new-member searches are so often left to chance. To some extent, it is simply a doctor's "busyness" with medical practice, but many other doctors just are not sure how to proceed. One cardiologist recently told us, "This is the first time I've ever had to seek out a partner; how should I go about it?" We hope this article will provide some guidance.

Starting Early

Assuming the decision to hire was made far enough in advance (an early decision vastly improves the chances of success), the actual recruiting process should begin much sooner than most physicians expect. We suggest that late Winter or early Spring of the year *before* a planned hiring (some one and one-half years before it) to be the best. In other words, recruiting at training programs should concentrate on the second-year residents and fairly newly appointed two-year fellows.

Contacting young physicians more than a year before they are available gives a senior doctor(s) a healthy headstart. The recruiting season is at its heaviest in the Fall or early Winter of a young doctor's final training year, and as a result efforts starting in November or December might be late to catch the most outstanding candidates. This is even true today with the increasing doctor supply, for a practice should strive to be ahead of its competition for those few "superstars." Since you want to recruit the best, recognize your need to be early to attract them.

Some doctors only decide to expand or replace within a few months of the anticipated July 1 starting date. They will be best served addressing their efforts to *both* second and third year residents (and equivalent fellows). While they might be fortunate in locating an "ideal" candidate for July 1, the odds will be against them. Too many good physicians will already have been signed up. Those late-starting doctors' best alternatives may thus be to develop the best doctor choice for the following July 1, being early on that search and late for the immediate search.

Our recommendation assumes recruitment from residency and fellowship training programs, for those two avenues are the most common source of new

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physician-members. Other sources include the military services, from which resignation dates vary throughout the year, and various group, clinic and public health service employments which may be proving unsatisfactory. Off-schedule recruitment might locate highly desirable applicants from these sources sooner than anticipated, but a practice cannot depend on it.

Overall, our timing emphasis is based on one overriding philosophy. A doctor should insist on continuing the efforts and being patient until the "ideal" candidate presents himself or herself and is hired. Thus, it is best to start early with built-in time for critical selection.

Getting the Word Out

The recruiting process should start with a deliberate effort to attract the greatest number of qualified applicants. One can never tell where that one "best" person will come from, so a large pool of choices will increase the percentage likelihood.

Physicians tend to dislike this advice despite its inherent logic. They protest that they are too busy to sift through countless curricula vitae, endure dozens of interviews, telephone and in-person interviews, choosing instead to contact just a few nearby training program chiefs and hope for a lucky find. However, the subject is simply too important for less than maximum effort; and the time problem should instead be solved by structuring all succeeding steps as efficiently as possible.

There are three main sources from which to develop a pool of applicants, all of which should be considered. Let us discuss each:

1. *Physician search organizations.* For the extremely busy physician or practice, a search firm can be a worthwhile investment. Care must be taken that the firm knows private practices, for firms specializing in large clinics or hospitals are sometimes not sensitive to the needs in private practice. While search firms are paid on a percentage of the first year salary of the new physician, be wary of those who require you to sign an exclusive contract. You'll be obligated to pay their fee, even if the candidate comes from your own source. It is best to pay as you work with them, perhaps with 50% or more of the fee due only on successful completion—yet you are free to pursue your own sources as well.

2. *Journal advertising.* Major journals of each specialty or subspecialty along with state and country journals carry numerous want ads placed by practitioners and clinics seeking physician-employees. The sheer number of ads carried each month, combined with a corresponding fear and distrust that most of the inquiries will be underqualified, tends to weaken doctors' enthusiasm for this approach. Yet we consider journal advertising to be a worthwhile, cost-efficient part of the overall effort.

Receiving too many responses from an ad is far better than not encountering interested, qualified applicants at all. A physician must recognize that many of the respondents will not fit a practice's requirements of quality training and performance, yet one should simply undertake to screen each response very critically before preceeding further. Even if just one or a few of the respondents become potentially excellent candidates who would otherwise have been missed, journal want ads should definitely be used.

Journal ads should be drafted with a bit of flair, for too many of them tend to suppress response by their sameness in style and language. We recommend oversized ads with text attempting to convey a positive image of the practice involved. The difference in cost between a standard half-inch want ad and a two-inch bordered ad is so slight in relation to the subject's importance that any saving in cost would be a false economy.

The ad might thus contain a bold heading, extra blank space above and below the first and last lines and a centered title to attract readers' attention. Its text should describe the practice's attractive characteristics and any specific qualifications required of its applicants. It should, in effect, be a tool to "sell" your practice and your location enough that qualified doctors will inquire further.

Many inquiries might flow from a single ad, and hence the text should request a cover letter and a curriculum vita. The practice itself should not be identified specifically, the text instead calling for submission to a box number usually provided by the journal. This approach enables critical culling of all responses before deciding who should be considered further.

Even if one month's ad in one journal produces a number of responses, the best policy is to advertise in several quality journals for several months in a row. The time and dollar costs are small compared to the possibility with a later or different ad will be seen by the ultimately best choice for "partner." Journal ads need several months' leadtime in some instances and this should also be recognized when considering timing.

3. *Training programs.* Direct contact to chiefs of residency and fellowship training programs is usually the most successful way to find well-qualified practice partners. Unfortunately, however, many hiring doctors take less than full advantage of the source.

A letter describing one's need for a quality young doctor should be prepared and sent to the chief of *every* well-regarded training program in the country. The effort should not be limited to a handful of programs within the practice's geographic region—where a young doctor happens to be training bears no consistent relation with where he or she might choose to settle.

If the hiring doctor knows the training program chief even casually, an introductory telephone call should precede the letter to give it maximum impact. Once in awhile, the chief might happen to name a favorite resident or fellow in that conversation, from which the hiring doctor might contact that young individual directly.

After the department chief hopefully reads the letter, it will probably be tacked onto a bulletin board in the residents' lounge or educational office. It will thus have to compete with many other letters and notices seeking the young doctors' attention, so it must be carefully drafted as a "selling tool." Your letter needs to be noticed!

We advise preparing a fairly short letter which briefly describes what qualifications are being sought and why the opportunity is a superior one. It should call attention to an attached memo containing more detailed description. That memo should fully describe the practice and its physician-member(s), the hospital(s) involved and the medical climate of the community. Describing the community itself as a place to live, raise children and enjoy recreational and cultural features is, of course, equally important. In these times of two career families, mention of general employment opportunities is an added selling feature.

The memo, which presumably will be included on the bulletin board, should plainly show its purpose of interesting the best young doctors. It should convince them that there is a prarticularly good private practice opportunity which deserves to be pursued. The residents reading the memo should thus be invited to respond by letter, enclosing a c.v. for the hiring practitioner's initial screening review.

Initial Screening of Responses

Since a practicing physician will have limited time, the supply of respondents must be critically culled down. Many of the blind ad responses will be inappropriate on their face and can be marked for the "no" file. Letters personally addressed to rejected doctors who had answered the training program solicitation should, out of courtesy, briefly state that the qualifications are off-line. It is usually not necessary to respond to people who are inappropriate and who responded to a Journal ad. Some physicians, however, feel these too should be acknowledged.

The initially interesting responses might be held for a few weeks or a month. Each of them should be "graded" on a scale of one to ten and kept in that order until enough applicants' c.v.'s have been reviewed. In this manner the most favorably appearing inquiries will receive first attention when the next step is taken. Of course, any response which appears on its face to present an absolutely ideal candidate could be pursued immediately.

Responding by Telephone

When ready to proceed, the hiring doctor should devote an evening or evenings to telephoning the top-ranked applicants. The discussion can describe the practice more fully and pursue further the young doctor's true level of interest. Conversation about clinical aspects of the specialty and general non-medical interests are equally valuable so the parties can begin feeling each other out as real people. So often the intangible "chemistry" is as important as the clinical skills. Thus, the personality is important and should not be overlooked.

The hiring doctor should make notes of impressions as the conversation takes place. Margins of the cover letter and/or c.v. are ideal for those notes since the impressions would thus be kept with the young doctor's identifying characteristics. The observations should include personality features, training or clinical concerns and any "gut reactions" one might have. This must be done during or after each call, for applicants tend to blend together when several are done consecutively.

The telephone discussion should not automatically result in an invitation to visit the practice. There may still be a variety of applicants deserving follow-up, and the hiring physician must avoid being trapped into too many time-consuming personal interviews. Each applicant can be told that the phone call is a preliminary contact and that a number of other respondents are still to be telephoned. A promise of either an invitation to proceed further or a brief letter thanking them for their interest but stating the qualifications, training or experience are not quite right would be appropriate within several weeks.

Checking References

There is no sense in consuming valuable doctor time to interview possible candidates who might later be rejected for easily discernible reasons. Accordingly, a hiring doctor should first very deliberately check references on any applicant who appears attractive on paper and by telephone.

While a reference check will be most successful directly in person, telephone calls will usually have to suffice. In any event, a doctor should not rely on letters since people will rarely express their true impressions of other people in writing.

The chief of the young doctor's present training program obviously must be contacted, and we recommend telephoning other physicians the candidate has named as being involved in his or her training. Chiefs and other medical supervisors at prior training programs and/or work experiences should likewise be contacted. If a busy practitioner objects that so many phone calls will take too much time, just consider how much time will be wasted in proceeding with the wrong candidate.

Before telephoning references, the physician should have a clear written outline of the questions to be asked. While concerns over clinical experience and competence are obvious, a number of other concerns deserve equal attention especially in the close working relationship of a private practice. Ask, for example, how nurses, clerks and reception people have responded to the young doctor; someone with an overbearing attitude towards subordinates may well become a difficult partner a few years hence. Similarly, one's demeanor with patients must be important. Whether the chief or other supervisor has heard of any complaints in these personal aspects of training and/or practice should thus be a virtually automatic question.

Here are a few special questions that might be asked along with the described line of inquiry: Were assigned projects performed on time? Were there any personality conflicts with his/her peers? With any of the seniors? Did he/she demonstrate any leadership qualities and, if so, how? Was he/she punctual? Was there any indication that family or personal matters might interfere with his/her work performance? What are his/her best characteristics? What are the weakest?

Making careful notes of each reference person's responses and including impressions of those answers' feeling and enthusiasm is important. Pay particular attention to voice inflections, hesitations or other tell-tale signs that the person is less than enthusiastic in his or her comments. An axiom in reference checking is that one needs to pay attention to what is not said as much as to what is. Such notes should be clipped with the other materials on the same candidate for handy evaluation. The overall supply of material will hopefully lead to an intelligent decision as to which individuals should actually be invited to the office.

First Interviewing

Those selected few physicians, no more than five as a "first round," should then be invited to meet with the doctor or doctors at the office. Assuming the applicants are within a few hundred miles of the office, each first interview might be planned to last no more than three hours. It will thus serve as a business interview—a first, get-acquainted opportunity to jointly determine whether more serious discussions should follow.

We believe too many senior doctors improperly create overexaggerated first interviews. The sessions are daylong social and business gatherings from which commitment to actually practice together tend to develop without critical evaluation. Luxurious dinners, evenings with spouses in seniors' homes and the like just are not conducive to early "feeling out" efforts.

The senior doctor(s) should be extremely critical during these preliminary interviews. The practitioner will hopefully take notes of impressions, perhaps using the young doctor's resume page or a separate sheet for such observations. Particular attention should be given to impressions of the applicant's capacity to interrelate with people and to communicate well, overall personality and the like—not just to indications of clinical or academic ability. The reason for this emphasis is simply that practice relationships fail more often because of interpersonal difficulties than professional deficiencies. The "chemistry" needs to be right, for no matter how clinically competent if the right personality mix is not found, the relationship will be hard pressed to be successful.

The initial interview can be brought to an end on schedule by the senior doctor(s) simply thanking the visitor for coming to talk. It should be made clear that others are being interviewed, after which a few people will be invited back for extensive discussion. In any event, an interviewed physician must be given the courtesy of some follow-up within a promised period of two to four weeks.

Second, In-Depth Meeting

The process will hopefully have identified one person or a few individuals who might be ideal candidates for a long-term practice relationship. If not, we are relatively unenthusiastic about pursuing lower rated candidates because doctor-level selection is too important for quality compromise. It may be better to forego second interviews and resume the entire search process once again—even if it means waiting longer to add a physician to the practice.

A selected doctor should at this stage be invited to spend at least a full day and evening with the senior doctor or group. Each physician-member of a group practice might then engage in one-on-one discussion, and the lead or solo doctor should plan on devoting many hours of attention. In addition to long, rambling discussions about all matters affecting a future relationship, the senior doctor can take the candidate for a tour of the hospital(s) served and even of the community.

There should be a few hours during which the young doctor can actually work side-by-side in practice with the senior. A candidate can learn better what the practice is really like in a real-life setting, while the senior(s) can observe how he or she performs under regular practice demands. It allows both sides to let their hair down a bit. Although concerns over malpractice insurance, hospital rules and/or patient acceptance may interfere with this opportunity, it should be attempted to whatever extent possible.

We prefer structuring the discussions in a business format—over a desk in the office. The long-term relation being considered is a business and professional one much more than a social friendship, so the talk should reflect that future. A pleasant dinner, perhaps with spouses, may be a good interlude but one rarely accomplishes the same level of meaningful talk in that environment.

Non practice aspects of life are, of course, equally important to a well-balanced young physician. Therefore, he or she should be given some free time to learn about the community, its housing, schools, cultural and recreational advantages and its features for all members of a family.

The business discussions can focus on professional plans for the practice, its present and projected future finances and the young doctor's personal goals and concerns. We encourage complete candor at this point, even showing the practice's financial reports, consistent with one's intention to seek the young doctor as a peer.

An outline of what are tentatively considered reasonable first-year employment terms and ongoing partnership details should be presented, though it should be framed as preliminary. One must maintain the concept that this in-depth interview day is still just another step in each side's selection process. Even if only the one young doctor is under consideration, it should nevertheless appear that no real decision has yet been made and that other candidates apparently are still in the picture.

Moving to Final Negotiations

After this extensive day or days of involvement, each side should have a good idea whether practicing together may indeed be desirable. The senior doctor or group should critically review all the materials and personal impressions on each remaining candidate and decide with whom discussions should be continued. If the selected young doctor (or perhaps several doctors who are still highly desired) also remains interested, then there should be third, fourth and maybe even more specific discussions.

The routine would at this stage have changed from one of selection to one of courtship—promoting the practice and working out the details of that desired relationship. Having moved through this process of careful recruiting and selecting, the young physician who receives final attention will have much greater potential to become an excellent partner—both professionally and personally.

"BAYB DOE" REGULATION was invalidated by the U.S. District Court in New York. The ruling affirms that the federal government should not become involved in the medical treatment of severely handicapped newborns. In a statement, Board of Trustees Chairman John J. Coury, Jr., MD, said that the AMA was "elated" with the ruling. President Frank J. Jirka Jr., MD, added that the AMA believes the care of these newborns should be the responsibility of the parents, in consultation with their physicians and other professionals on the medical treatment team. The AMA—joined in the suit by the American Hospital Assn., American College of Obstetricians and Gynecologists, American Academy of Family Physicians, Hospital Assn. of New York State, and the Assn. of American Medical Colleges—argued that the U.S. Dept. of Health and Human Services exceeded its authority when it issued the regulation. The regulation required that notices be posted in hospital nursing stations. The notices would warn that withholding food or customary care from handicapped newborns was a violation of federal anti-discrimination laws. HHS also encouraged the formation of voluntary hospital-based "infant care review committees" to investigate cases of suspected neglect. In an earlier suit, HHS had asked the court to direct University Hospital in Stony Brook, N.Y., to comply with its demands for Baby Jane Doe's medical records. The government claimed it needed the records to determine whether the infant had been a victim of discrimination under Section 504 of the Rehabilitation Act. The court in that case ruled that Section 504 does not authorize HHS to interfere in medical treatment decisions involving handicapped infants.

—AMA *Newsletter,* May 30, 1984

Human Health Effects of Hazardous Chemical Exposures

NATIONAL ACADEMY OF SCIENCES

Introduction

This report is limited to research on the human health effects of hazardous exposures to chemicals, both man-made and natural. Although many physical factors, including ionizing and nonionizing radiation, are of public health importance, they are not included here. Nor did the Panel consider effects on the environment.

It should be recognized that personal habits, including cigarette smoking, unquestionably have major health impacts; and other factors, such as dietary constituents, may also be important. The initiatives proposed here should contribute a better assessment of the nature, variety, and extent of chemical threats, whatever their source, to the human population.

The extent of exposure is an indispensable component in any evaluation of the effects of hazardous chemicals. Research on means for estimating exposure by environmental monitoring, although very important, is beyond the purview of this Panel's study. One major proposal, however, deals with the estimation of individual exposure by the use of biochemical markers.

Many decisions made by the public and private sectors in relation to the control of risk of chemical exposures have had important economic consequences. Federal agencies and industry have often been compelled to make such decisions in the face of large scientific uncertainties. No amount of research can eliminate all uncertainties associated with assessing the risks of exposure to potentially hazardous chemicals or eliminate the controversial judgments inherent in any decision about control of chemical exposures. Yet there are opportunities to reduce scientific uncertainties and to increase the public's confidence that health is protected and that the economic consequences of imposed chemical control are justified. Recent dramatic advances, especially in molecular biology, have opened up the possibility of making substantial progress in reducing the scientific uncertainty in such decisions. Some of the best opportunities are of a fundamental nature that are likely to greatly enhance the ability to directly determine individual exposure, preclinical signs of disease, and chemically related illnesses in humans. Other promising efforts offer the prospect of greatly improved interpretation of laboratory data on possible chemical effects.

Of the many possible areas of potentially important and fruitful research, this Panel is recommending six that offer particular promise and are uniquely timely. Other important areas examined by the Panel included neurobehavioral effects, immunotoxicity, and organ-system studies, but they were eliminated from the Panel's primary recommendations at this time. These six areas were chosen based upon the Panel's belief that they offer the greatest prospect for making advances in our understanding of scientific issues that are likely to be pivotal in chemical risk decision making. Some of the initiatives relate to the improvement of existing assays; however, until such improvements are effected, existing methods must continue to be used. Some of the initiatives indicate that substantial progress can be made with research of several endpoints using human cells and tissues; however, the Panel recognized that several technical and legal considerations need to be resolved before such tools can be fully implemented and that for many other endpoints—beyond those covered in this report—far greater technical difficulties are anticipated before viable assays become generally available.

The six topical areas, for which priorities were not established, are:

I. Research to improve the basis for dose and interspecies extrapolations to humans.

II. Research into prediction of the effects of multiple chemical exposures.

III. Improvement in approaches to the determination of reproductive and developmental effects of chemicals.

IV. Development of cellular and molecular markers of exposure to chemicals and markers of preclinical effects.

V. Development and evaluation of means to distinguish among chemical cancer-causing agents on the basis of modes of action.

Report prepared by the Research Briefing Panel on Human Health Effects of Hazardous Chemical Exposures, Committee on Science, Engineering and Public Policy, National Academy of Sciences, Washington, D.C.

VI. Expanded use of existing federal data collection activities for assessing human health effects.

I. Research to Improve the Basis for Dose and Interspecies Extrapolations to Humans

NEED: Control decisions for human health are based largely on extrapolation from tests on laboratory animals. The qualitative and quantitative biologic differences between test animals and humans vary substantially. Therefore, improvement in making such extrapolation is needed.

RECOMMENDATION FOR PROMISING RESEARCH: Comparative studies—e.g., on enzyme patterns and repair mechanisms—that use, in the case of humans, surgical and autopsy tissues.

ANTICIPATED IMPACT OF RESEARCH: Research to establish the qualitative and quantitative differences over a wide range of doses between test animals and humans can improve toxicologic predictions.

RATIONALE: The information available to make judgments about the possible effects of exposures to chemical substances often consists only of results of laboratory tests on species other than humans. Judgments made on the basis of such information are inevitably weak, because of a lack of understanding of the factors determining interspecies similarities and differences in responding to chemical agents.

Interspecies variations in responses to toxic chemicals can arise from differences in many characteristics, such as genetic inheritance; enzymes that activate and inactivate toxic materials; intracellular pathways of toxicity; membrane biochemistry and receptors; absorption, distribution, storage, and excretion; and physiologic differences in particular organs. Through the study of these differences between humans and test species (including the use of organs and cells in culture), it should be possible to improve greatly our ability to interpret laboratory data in terms of potential risks to humans.

Exacerbating the problem of dosage extrapolation and interspecies comparison is the increased heterogeneity of the genetic mix as one proceeds from purebred, genetically homogeneous strains of mice to the human population. Genetic composition and expression are dominant factors in determining the cellular response to chemical insult. Knowledge of regulation of expression is still rudimentary, but some methods to evaluate differences in "genetic potential" are now available. Such methods must be used, if we are to recognize and evaluate differences in susceptibility arising out of human genetic diversity.

Improvement in the scientific base for dosage and interspecies extrapolation underlies improvement in the basis for judgments about chemical-related health risks to the human population. Such improvement is now possible through exploitation of increased understanding of a number of areas, including gene expression, DNA repair mechanisms, enzyme induction and specificity, developments in cell-culture techniques, and advances in cell biology.

A number of specific subjects of particular promise that should be pursued are noted below:

1. Differences in bioactivating and protective enzyme systems and of repair systems should be studied to increase understanding of differences in pathologic response between humans and test species.
2. Human and laboratory animal genetic homogeneity should be explored to gain the knowledge needed to recognize and evaluate differences of susceptibility arising out of human genetic diversity and to enhance extrapolation of laboratory results to susceptible members of the genetically diverse human population.
3. The role of physiological characteristics, such as lung structure and function, should be pursued in concert with molecular and biochemical explorations.

Thus, it is recommended that a focused program of research be undertaken to improve the basis for dose and interspecies extrapolations of chemical risks to humans.

II. Research into Prediction of the Effects of Multiple Chemical Exposures

NEED: Most chemical hazards involve concurrent or sequential exposure to multiple chemicals, e.g., product mixtures, toxic wastes, cigarette smoke, and pollutants in air, water, and the workplace. The scientific basis for evaluating health effects of such mixed exposures at often widely differing dose levels is extremely primitive.

RECOMMENDATION FOR PROMISING RESEARCH: Study of mechanisms by which chemicals alter biologic responses to yield addition, inhibition, or synergism of effects.

ANTICIPATED IMPACT OF RESEARCH: Such research can substantially improve ability to assess the health effects of environmental chemical exposures.

RATIONALE: Although study and control of environmental chemicals have necessarily focused on individual compounds, it is obvious that humans are exposed to a multiplicity of agents in their daily activities. Most chemical products in commerce and nearly all environmental pollutants—whether in the workplace, from hazardous-waste sites, water-effluent streams, or formulated products—are complex mixtures. To the extent that the effects of chemical mixtures differ from those of their separate components, there is an important need to develop approaches to the prediction of the effects of the mixtures, so that the basis for making control decisions about exposures to them can be improved. The needed studies can be conveniently divided into two types: 1. those focusing primarily on interactions among several potentially hazardous environmental chemicals, and 2. those evaluating interactions among environmental chemicals and other agents, such as foods and drugs.

Toxic chemicals can produce independent, additive, synergistic, or protective effects. In some situations, not only the extent but also the type of toxic effect of several chemicals together differs from the sum of each of the chemicals acting alone. Combined exposures can result in effects in different organ systems or in different toxic effects. Our understanding of the mechanism of action of individual agents has in a few instances begun to allow the prediction of effects of multiple agents, but much more information is needed.

Considerable data are now available on the effects of exposures of laboratory animals to specific chemical agents with regard to their abilities to activate or deactivate other chemicals. Studies in this area should be extended to the human as an aid to elucidating the underlying sources of the varied sensitivities of persons exposed to toxic chemicals.

Future studies should emphasize not only the biotransformations that lead to interactive effects, but also other processes, such as the absorption and distribution of chemicals. For example, with respect to the effect of one chemical on the absorption of another, competition for receptor sites in cellular membranes may be important in hormonal mediation. Such processes should be studied to determine the circumstances in which competition may be important.

An overall emphasis in future studies, wherever possible, should be on developing an understanding of general classes of compounds as an aid in predicting the nature of interactive effects. Such studies should complement the research on dosage and interspecies extrapolation described in Section I.

The results of all these studies would be valuable in guiding decisions about the many complex mixtures in commerce and in the environment. They would be extremely valuable in establishing priorities for the cleanup of multichemical hazardous-waste dumps.

Thus, it is recommended that there be a substantial increase in research into ways of predicting the effects of multiple chemical exposures at various dose levels.

III. Improvement in Approaches to the Determination of Reproductive and Developmental Effects of Chemicals

NEED: Current means for evaluating chemical injury to the reproductive function are of limited breadth and uncertain reliability, as are means for assessing chemical injury to the newborn.

RECOMMENDATION FOR PROMISING RESEARCH: Expanded research aimed at understanding mechanisms of chemical injury to the reproductive function.

ANTICIPATED IMPACT OF RESEARCH: Such research is likely to increase the reliability of experimental approaches and assessment techniques for evaluating chemicals that may cause reproductive abnormalities or birth defects.

RATIONALE: Various incidents of the past few years have increased public awareness of the potential for reproductive and developmental problems associated with exposure to hazardous chemicals—for example, the serious birth defects associated with thalidomide use during pregnancy, male sterility resulting from dibromochloropropane (DBCP) exposure in the workplace, vaginal cancer and adenosis in the daughters of women who were treated with diethylstilbestrol (DES) during pregnancy, fetal alcohol syndrome in the offspring of women consuming alcoholic beverages during pregnancy, and increased risk of spontaneous abortion in women who work in surgical operating rooms. As a result, both private and government organizations have been compelled to address potential reproductive and developmental effects of chemical substances to which humans are exposed. But the significance of the effects observed in current reproductive and developmental toxicity tests with respect to humans is unclear; accordingly, the control actions that should be instituted are uncertain.

The development of the ability to determine heritable changes brought about in the genomes of sperm and egg by exposures to toxic substances constitutes a pressing problem, because injury may persist and be expressed in later generations. The Panel believes that advances in molecular biology will help make possible the direct examination of regulation and expression of the human genome and its modification by chemicals.

The Panel has identified several areas of scientific inquiry that may contribute to the development of reliable tests for reproductive and developmental injury. These include research into:

1. Ways in which chemical agents lead to male and female infertility;
2. Morphologic and biologic characterization of sperm as a basis for detecting and understanding the action of environmental agents;
3. Physiology of implantation and the early stages of the maintenance of the fertilized ovum, particularly as related to potential vulnerability to chemical agents;
4. Prediction of the delayed effects of chemical agents on offspring;
5. Relation of postnatal adjustment, growth, and maturation to chemical exposure; and
6. Reproductive ability of groups of humans exposed to certain chemicals, especially at high concentrations.

With the expanded information that would be provided from research on these subjects, it should be possible to develop more specific and more interpretable tests, whose results could shape preventive measures to reduce the likelihood of reproductive and developmental effects of environmental chemicals.

Thus, it is recommended that federally supported research into the mechanisms of chemical induction of developmental and reproductive effects be increased so as to improve the assessment of the potential of environmental chemicals to cause these effects.

IV. Development of Cellular and Molecular Markers of Exposure to Chemicals and Markers of Preclinical Effects

NEED: Sensitive means for estimating individual exposure to chemicals and for detecting early (preclinical) effects are urgently required.

RECOMMENDATION FOR PROMISING RESEARCH: Development and validation of techniques of high sensitivity and specificity for detecting the interaction of chemicals with, and their effects on, tissue components (DNAs, RNAs, hemoglobins, and other proteins) in humans for use in assessment of chemical exposure and risk.

ANTICIPATED IMPACT OF RESEARCH: Such procedures, if fully developed, would be powerful tools for direct evaluation of human exposure to environmental chemicals and its impact on human health.

RATIONALE: Current decision making about potentially hazardous chemicals is handicapped by the lack of anything more than fragmentary data on the levels of human exposure. Current approaches rely on projections derived from exposure models or on data from fixed monitoring stations. Generally, little information is available to measure or verify actual human exposure, especially to individuals.

Specific biologic markers of human exposure (as an adjunct to environmental monitoring) and of their preclinical effects offer a great opportunity to improve the ability to assess the effects of chemicals to which humans may be exposed.

There are several examples of promising research that should be pursued to develop and validate new clinical methods that would enable more accurate description of human exposures and detection of preclinical effects. Such methods should also be validated for animal systems so as to strengthen animal to human extrapolations. Promising methods that should be pursued include:

A. Means for evaluating individual exposure:
   1. Analyses of expired air, blood, and urine that can be coupled with tests of toxic activity—for example, the application of short-term mutagenicity tests (e.g., the Salmonella/microsome test) to provide, inexpensively and rapidly, information on a portion of the body burden of mutagens.
   2. Analyses for covalent and noncovalent binding of toxic chemicals to proteins or other constituents of assayable fluids or cells to be used as indicators of low-level exposures.
   3. Highly sensitive and relatively rapid immunologic and chemical assays for identification of chemically modified nucleic acid bases that are excreted in the urine.
   4. Use of monoclonal antibodies to detect specific chemical antigens for rapid screening of potentially exposed populations.

B. Means for detecting early (preclinical) effects:
   1. Analyses of chromosomal alterations to detect genetic damage in peripheral blood cells (lymphocytes) of large exposed populations.
   2. Detection of toxic effects on the reproductive systems from studies of changes in sperm morphology, including the use of special techniques, such as staining of DNA with fluorescent dyes and the use of rapid-flow cytofluorimetry to detect changes in the DNA organization of the sperm head.
   3. Use of recent advances in gene cloning and DNA sequencing to study alterations in the genetic makeup of human cells directly.

With the further development and validation of these indicators, exposure assessments in humans will be strengthened; and these improved assessments will substantially increase the power of epidemiologic studies. Such measures will also improve the basis for extrapolation from laboratory exposures to human exposures. Potential applications include assessment of the consequences of human exposure in industrial and community settings and in connection with toxic-waste dumps.

Thus, it is recommended that support be increased for the development and validation of cellular and molecular markers of exposure to chemicals and of markers of preclinical effects of chemicals.

V. Development and Evaluation of Means to Distinguish Among Chemical Cancer-Causing Agents on the Basis of Modes of Action

NEED: Cancer induction in humans may often be the result of a complex series of chemical and biologic interactions. Yet, lacking full understanding of these processes, we continue to treat chemical causation of cancer as if it were a one-step process.

RECOMMENDATION FOR PROMISING RESEARCH: Research aimed at refining understanding of the stages of carcinogenesis, including "initiation" and "promotion," and the further exploration of possible fundamental differences, such as those between "genotoxic" and "nongenotoxic" carcinogens.

ANTICIPATED IMPACT OF RESEARCH: Such research may make it possible, in risk assessment and control decisions, to distinguish among potential cancer-causing chemicals on the basis of their modes of action.

RATIONALE: Current evidence indicates that carcinogenesis is a complex process that often involves the induction of a stable and permanent change in the genetic information of a cell (initiation), followed by successive stages that lead to the development of a malignant tumor. A number of factors, including chemical exposures and nutritional status, are known to affect the progression of initiated cells to tumors, either enhancing (promoting) or inhibiting tumor development. If the different modes of action of various chemicals in carcinogenesis were better defined and understood, it might substantially affect the way in which potentially hazardous chemical exposures are evaluated and acted upon.

Too little is known about the importance of man-made and natural environmental agents that may promote or inhibit tumor development. It is evident that man-made chemicals are not the only initiators or modulators of neoplastic changes. Some constituents of natural foodstuffs, uncooked or cooked, can act as initiators, promoters, or inhibitors of tumor formation; such naturally occurring factors may be important contributors and should be intensively explored.

A few chemicals—such as saccharin, TCDD, phenobarbital, PCBs, some chlorinated hydrocarbons, and bile salts—have been shown to induce tumors in animal tissues but show no evidence of genotoxicity; therefore, they may be acting through the promotion of cells previously initiated spontaneously or by unidentified agents. The number of environmental chemicals that may have similar promoting activity is unknown, because of the lack of bioassay systems for their detection. Recent advances in the fields of molecular and cellular biology offer prospects for obtaining information on the mechanisms by which promoting agents exert their effects. An understanding of the mechanisms of action of such chemicals is required for the development of appropriate test systems and the evaluation of their public health significance.

Substantially expanded research that may lead to improved understanding of the significance of promoting agents in human cancer incidence is recommended. Similarly, research should be performed to understand the mode of action of chemicals that may induce cancer without being genotoxic. A wide spectrum of new experimental models should be developed—in vivo models that use animal organs and tissues, cell-culture systems that use human cells and tissue explants, and in vitro systems adequate to permit definition of molecular mechanisms, (e.g., possibly the activation of cellular and viral oncogenes).

The Panel encourages the development of effective short-term tests for the bioassay of environmental chemicals for promoting activity, as an adjunct to those tests that can identify genotoxic initiating agents.

Atherosclerosis is now viewed by some as a proliferative process akin in some respects to cancer. Dietary factors seem to be involved in this process. The exact nature of the mechanisms involved remains to be discovered, but may involve mutation, as well as modulation.

The results of research in these areas are likely to improve our understanding of the differences in modes of action between carcinogens and modulators and may thus form a basis for new approaches to risk estimation and control of chemical exposure.

Thus, it is recommended that a research program be initiated to study differences in modes of action of substances involved in the development of cancer.

VI. Development of Ways to Take the Greatest Possible Advantage of Existing Federal Data Collection for Human Health Effects Assessment

NEED: The health impact of environmental chemical exposure of humans is poorly known and largely speculative. Indeed, it may be substantially less than has sometimes been alleged. Reliable estimates require careful epidemiologic studies.

RECOMMENDATION FOR PROMISING RESEARCH: Linkage of existing governmentally collected data sets (such as National Center for Health Statistics, Social Security, and National Institutes of Health data) would provide a useful and efficient basis for epidemiological studies.

ANTICIPATED IMPACT OF RESEARCH: If legitimate concerns over data privacy can be overcome, such linkage would dramatically improve our ability to assess the effects of chemical exposures of humans relatively rapidly and inexpensively.

RATIONALE: There are four events that it is useful to link: exposure, appearance of a preclinical marker, appearance of disease, and death. In the case of many thousands of persons, detailed information has been collected on all four events; but it has been collected at different times, and the sequence has never been linked so as to reveal important patterns. Cost-effective research could be undertaken if the obstacles to such linkage could be removed. For example, within a single federal agency—the National Center for Health Statistics (NCHS)—it would be possible to:

- Identify relationships among occupation, lifestyle, and many environmental characteristics to specific causes of death by linking information obtained on the National Health Interview Survey to deaths identified through the National Death Index (NDI);
- Identify preclinical markers of serious disease by linking information obtained in the Health and

Nutrition Examination Survey (HANES) to deaths identified through the NDI or, even better, by re-including some persons in HANES later; and
- Identify preconceptional and pregnancy determinants of disease by linking data from samples of births to deaths of infants identified through the NDI.

The possibilities are further expanded when one considers eventual linkages between data of NCHS and those collected by other federal agencies. Two come quickly to mind: Linkage between NCHS and the Social Security Administration (SSA) to link the SSA 1% sample of continuous work histories with deaths ascertained through the NDI, and linkage between NCHS and the National Institutes of Health (NIH) data. NIH, in the course of many very large case-control studies and even larger experimental-intervention studies, has assembled detailed environmental, social, and medical information on many thousands of normal persons (i.e., the controls in the case-control studies, the nonexperimental group in the intervention studies); those data should be followed through the NDI with causes of death linked to the information obtained in the NIH research.

These are only a few of many possibilities. Funding, although needed, is not now the principal constraint. The concern for privacy severely constrains efforts to link data. An approach needs to be developed to determine and protect important aspects of confidentiality —but only those aspects, because the linkages proposed here can provide information of great value to society.

Thus, it is recommended that the policy issues related to data linkage be addressed and that appropriate linkages be made so that existing federal data collection activities can be used to the maximal extent possible to assess the potential human health effects of chemical exposures.

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Medical Evaluations of Healthy Persons

AMA COUNCIL ON SCIENTIFIC AFFAIRS

How often should a healthy person be examined by a physician, and what procedures should the examination include? Are there criteria that can be used in selecting the procedures? At least since 1923, the American Medical Association has been concerned with such questions. An AMA report in 1947 recommended that a healthy individual more than 35 years old have an annual medical examination, not only to aid in the recognition of adverse environmental factors and habits of living, but also as a way of promoting the individual's vigor, physical and mental fitness, and quality of life.[1]

Realizing that the medical examination of healthy persons remains a matter of current interest and debate, the Council on Scientific Affairs (CSA) decided to reconsider AMA's past recommendations on the subject. The Council also considered the recent comprehensive report by a Canadian Task Force on periodic health examinations,[2] reports of the Institute of Medicine and the American College of Physicians[3,4] and the recommendations of various other organizations regarding specific procedures, such as the examination of cervical cytology.[5]

The Council hopes that the following statement will serve as a useful review and guide for physicians, patients and others who are involved in health care matters.

Earlier AMA Position

AMA's House of Delegates first referred to the examination of healthy persons in 1923, in a report that advocated an educational campaign for physicians. An important step was the publication that year of the AMA book, *Periodic Health Examination—A Manual for Physicians,* which underwent revisions in 1932, 1940 and 1947.[1] Among the physicians contributing to the 1940 revision were W.D. Alvarez, H.S. Diehl, Haven Emerson, C.M. Peterson and P.D. White.

Cooperating with the AMA's editorial committee were such groups as the American Heart Association, the American Society for the Control of Cancer, the National Tuberculosis Association, and the National Society for the Prevention of Blindness.

Physicians were indifferent to the concept of examining healthy persons, said the 1940 edition, and participation of the public up to that time had been inconsequential. Only certain categories of workers were undergoing periodic examinations, for example, those involved with hazardous substances and those in public transportation; also, some companies were becoming interested in health examinations of their executives. Yet, periodic examinations could aid the early detection and treatment of conditions such as tuberculosis, hypertension, obesity, anxiety and insomnia. Physicians performing examinations were advised not to offer promises of good health, nor to emphasize minor defects, but to measure the overall health status of their patients and help them modify adverse habits and environmental conditions in order to achieve a better quality of life.

The 1940 AMA manual advised physicians examining well persons to use simple procedures, such as the blood smear, hemoglobin determination and urinalysis, because of patients' sensitivities to high costs.[1] Physicians were encouraged to make health examinations more popular by discussing them at medical conferences; including the concept in medical school curricula; and introducing the subject to the public in various ways, for instance, through radio and newspaper interviews, demonstrations at fairs, descriptive pamphlets, and personal contacts with school officials and directors of children's camps. The manual also suggested a schedule recommending an annual examination for the healthy adult 35 to 60 years old.

In many respects, the 1947 AMA manual propounded modern ideas and concepts. For example, it noted that although physicians had a relatively good understanding of the well-functioning body, few had learned how to instruct their patients in maintaining it. The manual urged the physician to be aware of religious preferences, since such factors might influence the important variable of diet and affect psychological status and interpersonal

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Action of the House of Delegates (1982) Annual Meeting: Report D of the Council on Scientific Affairs *adopted.*

relationships. It pointed out that good health requires knowledge about exposures to physical agents such as radium and x-rays, and to chemicals such as lead, benzene, mercury, carbon monoxide and methane; that drugs are prescribed to meet temporary needs and should be replaced by other measures when normal physiologic processes are restored; and that physicians might give prescriptions for healthful living: "Walk at least 3 miles each day;" "Add an orange and cereal to your breakfast." The manual gave detailed attention to nutrition, listing ideal weight tables and low-calorie diets, and describing 100-calorie portions of many foodstuffs. Also, it advocated that physicians instruct their patients in sexual matters.

Recent AMA Recommendations

Since publishing the 1947 revision of the manual, AMA has taken a position on periodic evaluations only with regard to workers in industry. In 1965, the Council on Occupational Health prepared the report, "Guiding Principles of Medical Examinations in Industry," which was revised by that council in 1973.[6] According to the report, the objectives of health examinations are: to help workers maintain or improve their health; to detect the effects of harmful working conditions and advise patients about corrective measures; to improve workers abilities to perform their tasks; and to create ongoing health records. The examinations should be carried out under a flexible plan that recognizes individuals' special characteristics and needs, especially those that might be related to their age group, sex, specific tasks, and exposures to adverse chemical or physical agents. The report recommended that persons more than 45 years old have annual medical examinations to detect the degenerative disorders that may appear after that age.

Key Principles and Recommendations of Others

Because a cardinal tenet of the physician is, "First do no harm," the Council on Scientific Affairs believes that the safety of procedures to be used in the evaluation of healthy people is an important consideration. Other basic factors are *sensitivity* of a procedure, that is, its ability to identify those who truly are affected by a condition; its *specificity,* that is, its ability to identify those who truly are *not* affected by a condition; and its predictive value, which relates to the condition's prevalence. Also, the condition to be tested for in the healthy population should be responsible for appreciable morbidity; its natural history should be known; effective therapy or intervention against the condition should be possible; and the test procedure should carry a cost commensurate with the benefit and be acceptable to patients.

The comprehensive Canadian Task Force Report,[2] and the recommendations of the Institute of Medicine[3] and the American College of Physicians[4] take cognizance of the principles listed above. The Canadian Task Force Report is especially noteworthy. From 128 relatively common, potentially preventable conditions, the Task Force and its consultants, representing many medical specialties in Canada and the United States, selected procedures and activities pertaining to 85 conditions that would be utilized in examining healthy Canadians of all ages. Whether the Task Force recommended a given procedure or activity depended upon the quality of evidence from the biomedical literature, particularly that of clinical trials, and on the opinions of respected authorities. Conclusions of the Task Force appear in a 194-page monograph with 1,500 references.

The Canadian Task Force Report,[2] the report of the Institute of Medicine,[3] and the statement of the American College of Physicians[4] all conclude that periodic medical examinations of the healthy person should vary in content and frequency depending upon age and sex. The recommendations of the Institute of Medicine and of the American College of Physicians appear in Appendixes 1 and 2.

When the recommendations of all groups are considered, it is apparent that there is little unanimity of opinion, either about the frequency of periodic evaluations or about specific procedures. For instance, sigmoidoscopy is recommended by the American Cancer Society for persons more than 50 years old, every 3 to 5 years following two successive negative examinations a year apart,[5] but the Canadian Task Force and other groups do not recommend the procedure at all. On the other hand, several authorities recommend an annual test of the stool for occult blood.

Recommendations vary about the frequency with which cervical cytology should be done, but the American College of Obstetricians and Gynecologists advocates that the procedure be done annually. Also, there is some difference of opinion about mammography. The Institute of Medicine report recommends that it be done every 1 to 5 years depending on age (ref. 3 and Appendix 1), while the American Cancer Society recommends a baseline procedure between the ages of 35 and 40 years and an annual procedure thereafter.[5]

Variable definitions of what constitutes adequate history-taking and counseling might explain differences in the extent to which the several reports fail to mention an occupational history, and a history of exposure to ionizing radiation and of the use of medications. In the same way, some may assume that a physical examination always includes procedures such as examination of the breasts and rectum, and a hearing assessment. Routine chest x-rays are no longer recommended by most authorities, nor, ordinarily, are periodic serologic tests for syphilis. However, the Canadian Task Force and Institute of Medicine reports recommend that the pregnant woman have a VDRL, as well as a test for rubella hemagglutinating antibodies and one for anti-Rh positive antibodies.[2,3]

Current AMA Position

While it is unlikely that any group of physicians from different medical specialties would agree on the frequency of periodic medical evaluations, or on what procedures the evaluations should include, most would agree that thorough examinations of healthy individuals, combined with evaluations of their overall fitness and with counseling, are valuable. In suggesting the intervals for such examinations, it is wise to give considerable weight to the guidelines of medical specialty groups that have already developed recommendations for specific populations. Because the specialty groups may update their recommendations periodically, the practitioner should seek the most recent ones.

Good health for an infant begins with the parents before their infant is born, and especially with the health of the mother. Adequate medical care can help prevent hemorrhage and hypertension in the mother and prematurity in the infant, all of which are significant causes of morbidity and mortality. The Council believes that the recommendations of the American College of Obstetricians and Gynecologists are appropriate for the pregnant woman, and that her care should include visits to a physician every 4 weeks for the first 28 weeks of the pregnancy, visits every 2 to 3 weeks for the next 8 weeks, and then weekly visits until delivery.

For the care of infants, and for health supervision of children through the years of adolescence, the Council advocates the recommendations of the American Academy of Pediatrics (Appendix 3). The Academy's recommendations are flexible and emphasize the necessity of meeting the needs of each child; the recommendations also assume that the child has capable, responsible parents and does not have a significant health problem. The Academy recommends that the newborn infant be seen 2 to 4 weeks after birth, 4 to 5 more times within the first year of life, and thereafter every 1 to 2 years through age 21.

The Council believes that healthy young adults, for whom morbidity and mortality rates are generally low except for traumatic injuries, should have medical evaluations at intervals of 5 years until they are 40 years old. This recommendation is in agreement with that of the Institute of Medicine.[3] After the age of 40, the Council recommends periodic evaluation at intervals of 1 to 3 years, depending on the individual's occupation, present health status, past medical history and other personal characteristics. Thus, for persons about 45 years old, the interval might be closer to three years, while for those older than 65 years, the intervals might be closer to one year.

For many reasons, all recommendations must be viewed only as informed guidelines. One reason is that knowledge in the biomedical sciences is changing constantly. For instance, within the past ten years the use of a vaccine against Rh positive antigen in the mother's blood has become a major weapon against erythroblastosis fetalis in the infant; the treatment of hypertension has been found to be a useful preventive against stroke; and an appreciation has developed about the risk to infants of their mothers' use of alcohol.

Certain groups of healthy persons, because of genetic, occupational or socioeconomic factors, will require the use of non-routine test procedures, or more intensive surveillance than other persons. Among such persons might be, for example, workers with prolonged exposure to toxic chemicals or to ionizing radiation; an infant whose mother may have had an acute viral infection early in pregnancy; or a middle-aged man with a blood pressure of 145/90 mm Hg.

The physician's evaluation of a healthy person carries with it the obligation to arrange suitable follow-up care when the person is found to have a potentially harmful condition. Then, the patient's future examinations will be planned on the basis of what is known about the course of the condition and its optimal treatment.

Discussion

Although Americans are well acquainted with the idea of "preventive maintenance" for their automobiles, there is currently some public skepticism about the need for periodic medical examinations, as evidenced by recent articles in widely read newspapers and magazines. Yet, as indicated by scientific contributions such as the Canadian Task Force Report,[2] and according to the consensus of knowledgeable persons[7-9] medical examinations can be helpful in the early detection of certain treatable conditions, such as amblyopia, diabetes mellitus, cervical cancer, hypertension and glaucoma. For other conditions, such as poliomyelitis, motor vehicle-related injuries, lung cancer and chronic bronchitis, primary prevention is possible and can be fostered by the physician's discussion with the patient of risk factors and preventive procedures.

One of the greatest benefits of the patient's periodic visits to the physician is that through them, both persons have the opportunity to build the mutual trust and knowledge that will stand them in good stead, not only when acute illness may require the physician's care, but also when the physician attempts to foster those behaviors and activities that contribute to the prolonging of the patient's healthful and productive life.[10]

There is merit in undergoing an evaluation at a fixed time, such as close to an anniversary or a birthday. By having a planned periodic medical evaluation, the healthy individual can be assured that no risk factors have developed since the previous visit, and the physician can check any new findings against a relatively recent baseline. Such benefits of a planned examination should be considered along with matters related to cost.

It probably is as true now as it was in 1947, that physicians need to improve their abilities to instruct their patients about healthful living, the proper funtioning of mind and body, and how to achieve them. While great strides have been made since 1947 in the prevention of poliomyelitis and measles, and in the treatment of infections such as pneumococcal pneumonia, syphilis and tuberculosis, a modern approach to good health requires knowledge about recently appreciated factors such as the costs and yields of various procedures and the sensitivity and specificity of tests.

Conclusions

AMA has held a position favoring periodic examinations of well people since at least 1923. It is time to reemphasize some principles of healthful living and of proper medical care that were described in earlier years, adding certain newer concepts and considering the recommendations of several recent authoritative reports:

1. The periodic evaluation of healthy individuals is important for the early detection of disease and for the recognition and correction of certain risk factors that may presage disease.
2. The optimal frequency of the periodic evaluation and the procedures to be performed vary with the patient's age, socioeconomic status, heredity, and other individual factors. The evaluation of a healthy person by a physician can serve as a convenient reference point for preventive services and for counselling about healthful living and known risk factors.
3. The general recommendations presented here should be modified as appropriate in terms of each person's age, sex, occupation and other characteristics. All recommendations are subject to modification, depending upon factors such as the sensitivity and specificity of available tests and the prevalence of the diseases being sought in the particular population group from which the person comes.
4. The testing of individuals and of population groups should be pursued only when adequate treatment or intervention, and follow-up can be arranged for the abnormal conditions and risk factors that are identified.
5. Physicians need to improve their skills in fostering patient's good health, and in dealing with long recognized problems such as hypertension, obesity, anxiety and depression, to which should be added the excessive use of alcohol, tobacco and drugs.
6. Continued investigation is required to determine the usefulness of test procedures that may be of value in detecting diseases among asymptomatic populations.

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New SEER Data on Cancer Patient Survival

NATIONAL CANCER INSTITUTE

Newly updated statistics on the survival experience of cancer patients diagnosed with cancer between 1973 and 1980 show continued improvement, with 48 percent of all patients now curable. For a number of major types of cancer, more than two-thirds of all patients are curable, the National Cancer Institute has announced.

The impact of advances in the treatment of cancer can be seen even in a relatively short period of time. Within the past decade, substantial decreases have occurred in death rates for a number of cancers. This important trend cannot be explained by changes in the occurrence of new cancer cases.

The data are from NCI's Surveillance, Epidemiology, and End-Results (SEER) Program, which monitors the annual occurrence of cancer and the survival experience of patients in the United States. These new statistics for the 1973-80 study update the five-year relative survival rates that were calculated last year for patients diagnosed between 1973 and 1979. Last year, the reported five-year relative survival rate was 46 percent for all cancer patients, black and whites combined, diagnosed with cancer between 1973 and 1979.

Rates are calculated by an actuarial table and therefore include information on patients under observation for less than five years. Patients diagnosed between 1973 and 1980 were followed through December 1981. Complete five-year follow-up was conducted for patients diagnosed in 1973-76. The survival rates were revised upward in 1983 because an additional year of follow-up, 1981, was completed and because of inclusion of patients diagnosed in 1980. Except for cancers of the breast, prostate, and kidney, five-year relative survival is an indicator of curability in cancer patients.

Survival Rates

Some of the cancers with the most encouraging five-year relative survival rates, all races combined, are: thyroid, 92 percent; endometrium, 87 percent; testis, 82 percent; melanoma, 79 percent, bladder, 72 percent; prostate, 67 percent; uterine cervix, 67 percent; female breast, 73 percent; Hodgkin's disease, 70 percent; and larynx, 66 percent. Survival continues to be poor for some cancer, such as lung, pancreas, stomach, and esophagus.

For whites, the five-year survival rate is 49 percent for patients diagnosed with cancer between 1973 and 1980. This is better than the 47 percent reported last year. Black patients diagnosed with cancer between 1973 and 1980 have a five-year relative survival rate of 37 percent, up from last year's 35 percent.

Survival rates also were calculated separately for white children under age 15. The rate for these children diagnosed with cancer between 1973 and 1980 is 57 percent for all cancers, up from 54 percent last year. A rate could not be calculated for black children because the number of patients in the SEER registries was too small.

Further improvements in survival are expected, based on analysis of survival rates of less than five years. Increases in these rates suggest that five-year survival rates will be even greater after sufficient time has elapsed to observe all of these patients a full five years. For example, the two-year relative survival rate for testicular cancer was 83 percent for white men diagnosed between 1973 and 1976; the rate increased to 91 percent for white men diagnosed between 1977 and 1980.

FIVE-YEAR RELATIVE SURVIVAL RATES FOR ALL RACES COMBINED, BOTH SEXES, DIAGNOSED DURING THE YEARS:

CANCER SITE	*1973-80*
Endometrium (corpus)	87
Breast (females)	73
Cervix	67
Bladder	72
Prostate	67
Colon	50
Rectum	48
Stomach	15
Lung	12
Pancreas	3
Leukemia	32
Non-Hodgkin's lymphoma	46
Ovary	37
Kidney	50
Brain	22
Melanoma of the skin	79
Testis	82
Hodgkin's disease	70
Esophagus	4

*Rates are from the SEER Program, and are based on data from the population-based registries in Connecticut, New Mexico, Utah, Iowa, Hawaii, Atlanta, Detroit, Seattle-Puget Sound, and San Francisco-Oakland. They include patients diagnosed through 1980 and follow-up on all patients through 1981.

The four-year relative survival rate for white children under 15 years of age with acute lymphocytic leukemia increased from 53 percent for patients diagnosed between 1973 and 1976, to 73 percent for those diagnosed between 1977 and 1980. For oat cell lung cancer among whites, the one-year relative survival rate increased from 21 percent for patients diagnosed from 1973 to 1976, to 30 percent for patients diagnosed from 1977 to 1980.

Cancer Death Rates

The number of people dying of cancer yearly per 100,000 population has remained fairly level from 1969 through 1980, with an average increase of only 0.4 percent yearly. The annual number of newly diagnosed cases per 100,000 population has also remained relatively constant from 1973 through 1980, increasing an annual average of 0.6 percent.

However, some remarkable decreases in death rates occurred for some of the major cancers, as measured by the percent of change in the death rates between 1969-1970 and 1979-1980. For women, there were substantial decreases in the death rates for all cancers of the genital organs and a slight decrease for breast cancer; cervical cancer was down 40 percent; endometrial cancer, down 15 percent; ovarian cancer, down 10 percent; and breast cancer, down 1 percent. Even more striking were the decreases in death rates for women under the age of 50 for: cervical cancer, a percent decrease of 43; endometrial cancer, a percent decrease of 40; ovarian cancer, a percent decrease of 33; and breast cancer, a percent decrease of 13.

The most disheartening news, however, is the increase in the death rate for lung cancer among women. The death rate nearly doubled between 1969-1970 and 1979-1980, presumably due to the growing number of women who smoke. It is estimated that in 1984, lung cancer will exceed breast cancer as the leading cause of death from cancer among women. For men, the death rate for lung cancer increased by nearly one-fourth over the same period.

Other cancers with decreased death rates include: testicular cancer, down 46 percent; Hodgkin's disease, down 52 percent for men and 46 percent for women; and bladder cancer, down 17 percent for women and 6 percent for men. For white children under 15 years of age, there were decreases for the major cancers including acute lymphocytic leukemia, soft tissue, kidney, brain, Hodgkin's disease, and non-Hodgkin's lymphoma.

Since 1973, SEER registries have collected information each year on the occurrence of cancer and the survival experience of patients from a population-based sample of approximately ten percent of the United States population. An earlier NCI analysis provided rates by cancer site for patients diagnosed between 1970 and 1973, compared with rates from patients diagnosed between 1960 and 1963. These rates were from follow-up analyses conducted at a series of hospital registries at one population-based registry.

Although the SEER rates cannot be compared exactly with those from the earlier years, they do indicate that survival has improved for a number of major cancers. For other cancers, the new rates are similar to those previously reported.

Missouri Supreme Court Decision on Nursing Practice

AMERICAN MEDICAL ASSOCIATION

A recent decision by the Missouri Supreme Court allowing professional nurses in that state to perform pelvic examinations and recommend forms of birth control is being hailed by nurses and nursing groups across the country as a positive decision that could have far-reaching effects beyond Missouri's borders and into state nursing codes throughout the nation.

The case, Sermchief v. Gonzales, began in 1980 when the Missouri Board of Registration for the Healing Arts voted to prosecute two nurse practitioners who were working in family planning clinics in rural southeastern Missouri. The nurses had been conducting breast and pelvic exams, obtaining Pap smears and gonorrhea cultures, inserting IUDs, fitting diaphrams, administering oral contraceptives, treating vaginitis, and testing for minor vaginal infections and pregnancy under standing orders and protocols issued by five physicians working for the clinics. These physicians visited the clinics every two weeks to see patients referred to them by the nurse practitioners.

The Board also took steps to revoke the licenses of the physicians for aiding and abetting the anauthorized practice of medicine. The nurses and physicians then went to court in an effort to obtain a ruling that would include the duties being performed by the nurses within the scope of nursing as defined by the Missouri Nurse Practice Act.

The Missouri Nurse Practice Act had been revised in 1975 to eliminate the requirement that nurses had to work under the direct supervision of a physician. The revised Act no longer contains explicit prohibitions or limitations on nursing nor does it contain any specific legal recognition of the nurse practitioner. The law does, however, authorize professional (as opposed to practical) nurses to perform "any act which requires substantial specialized education, judgement and skill based on knowledge and application of principles derived from the biological, physical, social and nursing sciences." In addition, the Act authorizes such acts "assessment, nursing diagnosis . . . and administration of medications," and clearly specifies that nursing functions are not limited to those specifically outlined in the law.

A St. Louis County Circuit Court ruled in favor of the Board, but on appeal a Missouri Supreme Court Judge reversed the decision and found that:

1. the Missouri Legislature, by revising the Nursing Practice Act in 1975, had the "intent to avoid statutory constraints on the evolution of new functions for nurses delivering health services,"
2. the acts of the nurse practitioners clearly came under the purview of the Missouri Nursing Practice Act,
3. nothing in the law prohibited the continued use of physician standing orders and protocols, and
4. the right of the professional nurse to practice within the limits of his or her education and experience was recognized.

The Missouri case is interesting not only because of its potential impact on nursing practice nationwide, but also because of the tremendous numer of *amicus curiae* briefs which were filed with the Supreme Court. No less than 35 health-related associations or organizations and approximately 80 faculty members representing some 30 medical schools across the country filed briefs. The court even made mention of this in its opinion, stating that, "the appeal of this attracted amici briefs resembling a letter-writing campaign directed at a legislative body." Most of the briefs were returned to the senders unread.

State medical associations and national medical specialty society Executive Directors are advised to have their Legal Counsel review the Missouri decision to determine its potential impact on nursing practice in their respective states and specialty areas.

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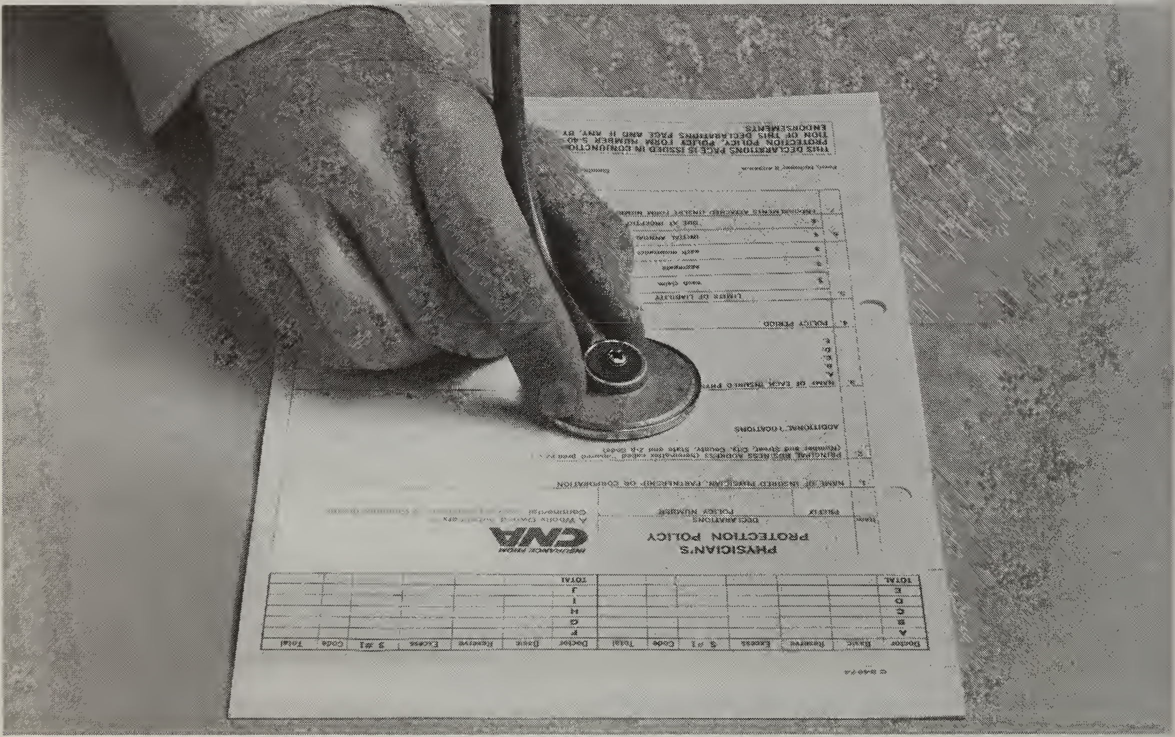

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The Message

An observation made by many both in and out of the medical profession is that the leadership of organized medicine is not getting its message across to the rank and file members to get them to respond appropriately on matters concerning their patients and practices as well as the profession itself.

Two incidents have led me to believe that such is the case and also ponder ways in which this problem can be remedied. In the recent session of the legislature when the "All Payors Bill" was before the Connecticut Senate and House, the Medical Society sent out two letters requesting the membership to contact their legislators either via telephone or letter, and also listed the names of these lawmakers and their districts. I asked several people if they had called or written and received no affirmative answers. I then decided to conduct my own unofficial poll and questioned twelve private practicing physicians if they had responded to the Society's request to contact their legislators. Of these twelve, nine denied they ever received any mail from the Society and the other three remembered seeing something but ignored it. Obviously, the Society's mail carries little weight.

On the other occasion, an attorney who was lobbying for a group, happened to be at a committee meeting which was being held in the Hall of the House. The committee was discussing a bill dealing with Podiatry. He stated that the podiatrists filled the gallery and had multiple speakers, whereas, the medical profession, whom this bill affected most, was represented by two speakers, neither of which was an orthopedic surgeon. My attorney friend was astounded at this poor showing on our part when the legislation being considered had a direct effect on all physicians and their patients.

It is a known fact that approximately half of the physicians in this country belong to the A.M.A., that many of us belong to the state society because, as in the past, malpractice insurance could only be obtained through a state sponsored program and as has been stated to me, the only reason for county association membership is the availability of good group insurance and investment plans. These reasons, and there are many more, attest to the leadership's failure at all levels of organized medicine in getting its message across.

In Connecticut, we have divided ourselves by eliminating unified membership (AMA, CSMS, County Association) whereby membership in one meant membership in all. More recently, when the malpractice insurance program changes occurred, some counties did not require belonging to the state society a necessity to obtain this type of insurance resulting in a further division between state and county organizations.

There are some bright spots emerging with physicians volunteering their services, at least on a county level, to serve on committees and get involved in the legislative process. But, volunteerism on the part of a few is not enough. We must discover new approaches and consider resorting to some of the old ones such as unified membership to get our message across. Possibly small groups should be formed who can be called into action with personal contact in the institutions where they practice, when the need arises.

But most of all, we must educate ourselves, and this includes all physicians, of the aims and aspirations of all of us to provide the best care for our patients at a cost which society can afford. Hopefully, all of us will lay aside our own battles in which we, as individuals have been vanquished and consider a broader view, before the entire war is lost.

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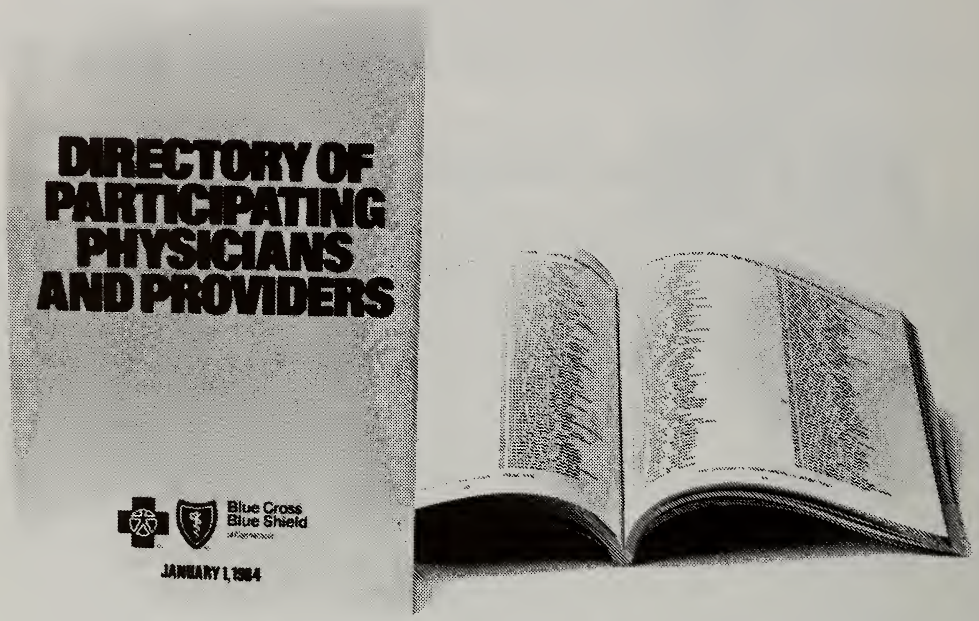

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Reflections From the Dean's Office

The 100th Anniversary of Local Anesthesia

ROBERT U. MASSEY, M.D.

Hearing the story of anesthesiology may begin a lifetime romance with the history of medicine; I remember reading about W.G.T. Morton and John Collins Warren in Logan Glendenning's delightful book, *The Human Body,* when I was 12 or 13 years old. The story that was said to end with "Gentleman, this is no humbug," was one of my favorites; there were few dramatic events in literature that could touch those of October 16, 1846, in the Ether Dome of the Massachusetts General Hospital.

In Connecticut, the rival claims of W.G.T. Morton, Horace Wells, and Charles T. Jackson assume the qualities of local legend; both our medical and dental students begin to take sides in the old controversy after they have visited the exhibits at the Hartford Medical Society. Then they read that the Georgia surgeon, Crawford W. Long, had been using ether since 1842. They raise all of the questions about the meaning of priority in discovery and invention, the connection between the spirit of the times and the work of scientists and inventors, the loss and gain that accompany anything new, and, perhaps most important, the human side of scientific discovery, the envy, pride, covetousness, and anger.

Since physical pain, intense and protracted, is the most dreaded of our afflictions, the power to control it safely should have been nearly the most eagerly sought after good of all. The Egyptians and the Greeks used opium perhaps with some effect, and there was alcohol and some other herbs in the long ages of pain which may have helped a little to ease the agony of the knife and saw. But not until the 19th Century and the beginnings of the humanitarian movement were two agents, already well known to chemists, employed to prevent pain in the way described by the author of Genesis: "And the Lord caused a deep sleep to fall upon Adam, —."

One hundred years ago, on September 15, 1884, Karl Koller's discovery of local anesthesia was announced at a Convention of German Oculists in Heidelberg; a month later in Vienna he read his paper which described the interest which both he and Sigmund Freud had taken in the alkaloid cocaine. He told of experiments upon animals and then later upon himself, by which he had proved that a two percent solution of cocaine would produce complete anesthesia of the conjuntiva and the cornea for seven to ten minutes. He reported that foreign bodies could be removed from the eye and operations for pterygium and cataract performed without pain.

Within a month R.J. Hall and William Stewart Halsted, working at Roosevelt Hospital in New York, had demonstrated that the injection of a four percent solution of cocaine around a cutaneous nerve would produce anesthesia throughout the area of distribution of the nerve. Later Halsted injected, by Hall's account, "the inferior dental nerve where it enters the dental canal." The subject, a medical student, developed complete anesthesia of his tongue to the midline, as well as of the gums and teeth on the same side. Halsted repeated that experiment the same evening on Dr. Hall with similar results: the dental and buccal anesthesia was complete for twenty-five minutes.

The dentists Wells and Morton had given general anesthesia to surgery; a surgeon repaid the debt by giving local anesthesia to dentistry. Discoveries and history are never quite that simple, but ophthalmology and dentistry would surely not have developed as they have without local anesthesia, and surgery would have been stuck in the 18th Century without the blessing of general anesthesia.

There was talk of the dangers of frustrating divine purposes and of the salutory effects of pain—always for the other person—and of the moral issue of pain relief in childbirth, talk which has not even yet gone away. In the calculus of loss and gain, anesthesia seems to be mostly gain. Halsted suffered, and so did others, from the unanticipated devastating effects of cocaine; some of those who worked with him even lost their lives, but Halsted, with the help of his colleagues, went on to greatness. According to his biographer, W. G. MacCallum, "the most brilliant of Dr. Halsted's actual discoveries was the conduction anesthesia that he produced by injecting the new found cocaine into a nerve."

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ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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LAW, MEDICINE AND PUBLIC POLICY

Deciding for the Incompetent Patient: The Role of Family Members

JOSEPH M. HEALEY, J.D.

The right of an adult person of sound mind to make decisions about his or her life is a widely recognized and accepted principle in American law. It arises out of a commitment to autonomy and self-determination and is the basis for the legal concepts of consent to treatment and refusal of treatment. The application of these concepts in concrete situations is frequently a complex undertaking. One area of particular concern is how the autonomy and self-determination of one unable to formulate or express preferences should be protected and respected. A recent decision of the Florida Supreme Court[1] addressed this concern and provided insight for those in Connecticut interested in these questions.

The facts of the case as presented in the Court's opinion are sketchy and incomplete. In April, 1981 the patient, Francis Landy, whose age and prior medical history were not described, was admitted to a Florida hospital and placed on a ventilator, having suffered brain damage, acute respiratory failure, chronic interstitial fibrosis and gastrointestinal bleeding. Over the next several days, his status continued to deteriorate and his physician judged his condition to be terminal. His wife presented the physician with a living will signed by Mr. Landy and two witnesses in 1975, stating that he did not wish to be kept alive through the use of extraordinary life support equipment such as a respirator. Mr. Landy was declared incompetent by a local probate court. His wife was appointed guardian of his person. She requested that all extraordinary life support systems be discontinued. Fearing potential civil and criminal liability, the hospital filed suit seeking clarification of its rights and liabilities in responding to the request of the wife-guardian. The trial court held that to avoid potential criminal and civil liability, it was required that a guardian be appointed, that a petition for authority to order termination be sought, and that court approval be granted. The appellate court affirmed the relevant portions of the trial court decision emphasizing that it was the Court's responsibility to determine what the individual would want done if he or she were conscious and competent. The Supreme Court of Florida reversed the lower court decision, holding that under the circumstances presented and in similar cases close family members or legal guardians could substitute their judgment of what they believe the terminally ill incompetent person, if competent, would have done under these circumstances. Prior court review would be available but not required. In its decision, the Florida Supreme Court addressed three questions: (1) the nature of the rights of terminally ill competent adults to discontinue extraordinary medical treatment; (2) the rights of terminally ill adults who are no longer able to express their wishes to discontinue the use of extraordinary artificial support systems; (3) the means by which these rights may be exercised. With respect to these questions, the Court concluded:

> "We have recognized that terminally ill incompetent persons being sustained only through use of extraordinary artificial means have the same right to refuse to be held on the threshold of death as terminally ill competent persons. Since incompetent persons may not exercise this right while they are incompetent, there must be a means by which this right may be exercised on their behalf, otherwise it will be lost. The means developed by the courts to afford this right to incompetent persons is the doctrine of 'substituted judgment.' Under this doctrine close family members or legal guardians substitute their judgment for what they believe the terminally ill incompetent persons, if competent, would have done under these circumstances. If such a person, while competent, had executed a so-called 'living' or 'mercy' will, that will would be persuasive evidence of that incompetent person's intention and it should be given great weight by the person or persons who substitute their judgment on behalf of the terminally ill incompetent.
>
> To be relieved of potential civil and criminal liability, guardians, consenting family members, physicians, hospitals, or their administrators need only act in good faith. For them to be held civilly or criminally liable, there must be a showing that their actions were not in good faith but were intended to harm the patient. Under the circumstances of this and similar cases, prior court approval is not required. The courts, however, are always open to hear these matters if request is made by the family, guardian, physician, or hospital. Disagreement among the physicians or family members or evidence of wrongful motives or malpractice may require judicial intervention upon the filing of an appropriate petition."[2]

Discussion of these issues will be continued next month.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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Connecticut Medicine

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Editorials

Alzheimer's Disease—A Family Dilemma

Advancing age brings with it an increasing susceptibility to intellectual deterioration and dementia. About 5 to 10 percent of individuals above 65 years of age are significantly demented to the point where independent existence becomes jeopardized. The majority of the elderly are usually capable of productive and independent existence. Dementia is a non-specific sign and indicates the presence of one of a great many disease states, some of which are more readily treatable than others, especially when detected early. Significant mental deterioration suggests disease processes which may be sub-divided into three major groups.

1. Toxic metabolic encephalopathies where the offending process is primarily external to the brain.
2. Dementias based on structural damage to the central nervous system.
3. Depression which may mimic dementia.

A great variety of structural diseases of the central nervous system could produce dementia. These include tumors, hydrocephalus, chronic infections and a variety of degenerative conditions.

Alzheimer's disease, called appropriately, "the disease of the century," is primarily a degenerative disease of the central nervous system producing dementia. Experimental evidence gathered in this country as well as abroad indicates that it is not an accelerated form of aging, but rather a specific disease pattern with selective neuronal loss in the cerebral cortex. Recent evidence indicates that these patients suffer from a selective defect of cholinergic transmission in the cortex. Experiments studying the glucose metabolism as well as the choline aceytl transferase activity in fresh cortical biopsy samples from patients with Alzheimer's disease, and controls, suggest there is a defect in the formation and metabolism of acetylcholine synthesis in the nerve cells of patients suffering from Alzheimer's disease.

Clinical trials using cholinergic agents in Alzheimer's disease suggest beneficial effects, especially with memory function. The cholinergic agents used include Lecithin, Choline as well as Physostigmine.

In this aspect, Alzheimer's disease has an obvious analogy to Parkinson's disease, which is caused by a lack of Dopamine neurotransmitter due to the loss of Dopaminergic Cells in the substancia nigra. Amelioration of the symptoms of Parkinson's disease is often accomplished with replacement of Dopamine and agents which increase the formation of Dopamine. It should be also noted that treatment of Parkinson's disease does not change the course of the progression of the primary degenerative process but only gives symptomatic relief.

Similarly, in Alzheimer's disease with the recent knowledge of defective cholinergic transmission and the beneficial effects of Lecithin, Choline and Physostigmine there is the hypothesis that once the proper dose of medication is determined by clinical trials, one may be able to help these patients to be functional for many years. A point of caution must be raised, Acetyl Choline deficiency may not be the only biochemical abnormality in this disease.

It is feared that with recognition of the symptoms and better diagnostic tools available, we may discover as many as 4 million patients are affected by Alzheimer's disease in this country, and that more than one-half of the beds in nursing homes will soon be filled with patients with this disease.

Publicity about Alzheimer's disease has created difficulties for physicians and family members. Fear and anxiety brings patients to physicians frustrated by inadequate means of treatment.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

In the meantime, until some effective form of therapy is available, family members are confronted with caring for this patient. Confused and bewildered, coping with the shock of their own changed futures, these family members need help with the daily caring for the afflicted.

Mrs. Martha Adams has concisely related her experiences, her personal observations, and ultimately the way in which she and her family members are coping gallantly in caring for her mother, who is suffering from Alzheimer's disease. This excellent article is a very useful guide for the patient's family as well as physicians involved in the care of these patients and gives us practical insight management until clinical and laboratory scientists can come up with better medical solutions for the problem.

Kanaga N. Sena, M.D.

Stratford, CT

How Much Salt for "Normal" Diets?

Salt restrictions for all diets, as a preventive public health measure, should not be made a blanket rule.

Measuring large numbers of unselected middle-aged people shows that about 10 percent have diastolic pressures in the 60 to 70 mm range, coupled with systolic pressures of 115 mm or less. While this is not a disease entity, mild hypotension can produce a vague feeling of lassitude in some, and more unpleasant symptoms in others such as a tendency to dizziness and excessive fatigability. Because of an occasional positional vertigo, such individuals may experience episodes of feeling faint, particularly in warm weather. If compensatory mechanisms are inadequate, in an upright position a low blood pressure may drop further to a point of reducing the blood supply to the brain.

For the primary prevention of hypertension, many authors have suggested a culinary reform in which the intake of salt is sharply curtailed not only for normotensives and potential hypertensives, but for the public at large. While such proposals have merit and are worthy of being promoted in health education, one should underscore the exceptions. In many cases of benign hypotension, adding more salt to the diet can make a notable difference in the tonicity of the skeletal muscles and in a feeling of well-being. If low-salt food habits are promoted as a general rule to benefit the public's health, there should be awareness of these exceptions.

Hans H. Neumann, M.D.

New Haven, CT

Benign Conditions May Prove Serious Under Long-Term Study

Some conditions thought to be benign may prove serious under long-term study, according to a new report from the Mayo Clinic. Robert A. Kyle, MD, says that patients with "benign" monoclonal gammopathy (abnormal production of lymph cells) may be at risk for myeloma, macroglobulinemia, amyloidosis or related diseases.

Writing in a recent issue of the *Journal of the American Medical Association,* he says, "No laboratory or clinical data initially differentiated patients, with benign gammopathy from those in whom serious diseases developed. Consequently, serial measurement of serum monoclonal protein is essential."

Two hundred forty-one patients with monoclonal gammopathy, but no evidence of other diseases, were followed for more than ten years, and in 19 percent of these patients, myeloma, macroglobulinemia, amyloidosis, or related diseases developed. A previous report on these 241 patients after five years showed that 11 percent had multiple myeloma, macroglobulinemia, amyloidosis, or malignant lymphoproliferative process.

The median length of follow-up in the current study was 13 years. At the end of the study patients were classified into four groups: patients without increase of monoclonal serum protein during follow-up (benign) (37%); patients with more than 50% increase of monoclonal protein or development of monoclonal urine protein (5%); patients who died of unrelated causes (39%); and patients in whom myeloma, macroglobulinemia, amyloidosis, or related diseases developed (19%).

The median age of patients was 64 years; only 4 percent of the 241 were younger than 40 years when the monoclonal protein was recognized. The median interval from recognition of the monoclonal protein to diagnosis of multiple myeloma was 98 months; macroglobulinemia, 115 months; and systemic amyloidosis, 92 months.

"Monoclonal gammopathies have been found without evidence of myeloma, macroglobulinemia, amyloidosis or related diseases in approximately 3 percent of persons aged 70 years and older in Sweden and the United States," notes Kyle. Other studies have found an incidence from 1.7 percent to 5 percent, and Kyle predicts that "the use of more sensitive techniques will detect a higher incidence of monoclonal protein."

The outcome for these patients is difficult to predict. In the Mayo Clinic study, the initial hemoglobin level, size of the serum monoclonal peak, number of plasma cells in bone marrow, and levels of normal immunoglobulin were not substantially different. According to Kyle, "analysis of age, sex, presence of small amounts of monoclonal light chain in the urine, serum albumin, and IgG subclass does not enable one to distinguish initially between patients with benign monoclonal gammopathy and those in whom various diseases will develop." Kyle concludes that "the most reliable means of distinguishing a benign from a malignant course is the serial measurement of monoclonal protein."

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

TESTING FOR TECHNIQUES IN THE DIAGNOSIS OF ALLERGIC DISEASES

To the Editor: The executive committee of the Section of Allergy of the Connecticut State Medical Society would like to respond to the article by Gillcash and Kamuzora in the February issue of the *Journal*[1] in order to provide a prospective on the burgeoning overenthusiasm for *in vitro* testing in the diagnosis of allergic disease.

In 1967, Wide, Bennich and Johannson[2] first reported a radioimmunoassay technique for diagnosing specific IGE antibodies in the serum of allergic patients. The RAST test has been a significant contribution to the field of allergy and immunology. The place of the RAST test in the diagnosis of allergic disease on a day to day basis is an issue that has come under a great deal of question.

Because of this, the Practice Standards Committee of the American Academy of Allergy and Immunology has reviewed this subject in great detail and has published a specific position statement on skin testing and RAST testing for the diagnosis of allergic disease.[3]

In its statement, the Academy points out that physicians who provide medical care for the patient with allergic disease should be properly trained and maintain their clinical skills. The diagnosis of allergic disease is made through a careful history, physical examination, and then appropriate laboratory procedures including skin testing and where indicated, RAST testing.

The complete medical approach to the diagnosis of allergic disease should be emphasized rather than the use of the laboratory examination by itself. The Academy also stresses that skin and RAST testing should be performed only when the indication for these tests are clearly documented and that either test used as a sole basis for formulating allergen extracts for allergy therapy is not in keeping with good medical practice. Unfortunately, there are many commercial testing laboratories throughout this country which are advertising the diagnosis of allergic disease simply by performing RAST examinations and without stressing the importance of a medical evaluation coupled with this test. Further, some RAST methodology is currently not reproducible and therefore not reliable.

There is really no disease that we treat in medicine where diagnosis is made by submitting 2 cc of blood to a laboratory. Yet the absentee diagnosis of allergic disease by performing a RAST test has become a highly successful commercial venture.

The Academy position paper compares RAST testing to skin testing for the diagnosis of allergic disease. It should be emphasized that both skin testing and appropriate RAST testing in skilled hands are reliable methods of diagnosis IGE mediated disease. The results of both tests are semi-quantitative and RAST testing is less sensitive than skin testing.

The position statement points out that RAST testing is preferable to skin testing only where certain conditions prevent allergy skin testing, such as wide spread cutaneous disease. Finally skin testing is usually far most cost effective than RAST testing. In this day when the practice of medicine has come under fire from the laity, governmental and economic groups being the major cause of inflation in this country, this issue must be faced. According to the Academy, RAST testing may cost from two to six times more than skin testing to the patient.

We feel it is completely illogical to encourage patients to undergo RAST testing as part of the diagnosis of an allergic disease when there is a more sensitive diagnostic test which is less costly to the patient. The myth of having a diagnosis made from a blood sample does not justify the cost of this technique being used as a routine allergy evaluation.

We believe that the RAST test is a fine immunologic tool and we have recommended it in certain selective cases to many of our patients. But we feel that it is the responsibility of the physicians and specifically allergists throughout this country to educate the insurance carriers and our patients as to the exact position of RAST testing in the diagnosis of allergic disease.

Robert Biondi, M.D., Norwalk; Robert DeBernardo, M.D., Bridgeport; Gerald Germano, M.D., Oxford; Louis Mendelson, M.D., Hartford; Carlton Palm, M.D., New Haven; Anthony Piccirillo, M.D., Wallingford and David Zolov, M.D., Danbury.

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The above letter was referred to Dr. Gillcash, who offers the following reply:

To the Editor: The letter to the Editor signed by the Executive Committee of the Section of Allergy of the Connecticut State Medical Society and citing the findings of the Practice Standards Committee of the American Academy of Allergy and Immunology is welcomed.

While the thrust of their letter revolves around RAST testing, the paper that the committee responded to was not about RAST testing at all.

RAST testing is a first generation polyclonal test subject to variable specificity and is clearly limited in scope pretty much as outlined in their letter.

The *Clinical Use of Specific Monoclonal Antibodies to Human IgE in Allergy Diagnosis* is very careful to include the word monoclonal in its title.

Acronyms are sometimes helpful and sometimes not. At any rate RAST and FAST are not just variations of each other. They are very different conceptually and technically with different sensitivities, and above all, completely different degrees of specificity.

The clinical usefullness of monoclonal antibody testing is as different from polyclonal testing as polyclonal is from cytotoxic testing. Those are big differences indeed.

Most clinically allergic patients are not seen or treated by allergists. Most are diagnosed and treated by primary physicians or by the patient himself. Look at the array of over the counter allergy medications available at any pharmacy.

We are in real need of a straightforward, reproducible, sensitive and highly specific in-vitro test that the primary care physician can use. The quality of referrals to allergists would be greatly enhanced by this tool.

The monoclonal system right now—handled correctly—provides this in about 80% of the cases. Improvements will follow.

The committee probably got caught up in a misunderstanding of what this paper discusses. I invite them to look at what the paper actually says and comment on it as it is presented.

Robert S. Gillcash, M.D.

Willimantic, CT.

(Position statement appears on following page).

Position statement

Skin testing and radioallergosorbent testing (RAST) for diagnosis of specific allergens responsible for IgE-mediated diseases*

This position statement reflects the state of the art at this time. It will be reassessed on a continuing basis as new data are developed.

The traditional approach to the specific diagnosis of reaginic (IgE-mediated) allergic disorders has been the use of skin tests of a variety of types. These tests have in common small quantities of allergenic extracts introduced below the epidermis. Within 15 to 20 min, a characteristic wheal-and-flare reaction can be observed in patients who have IgE antibodies that recognize one or more of the test allergens. This bioassay is highly sensitive, cost-effective, and safe when used by experienced personnel with due attention to technique and reasonable precautions.[1]

In 1967 Wide et al.[2] first reported from Sweden a solid-phase radioimmunoassay capable of detecting the minute quantities of allergen-specific IgE antibodies that circulate in the serum of allergic patients. Over the last decade, this in vitro test, the RAST, has been refined and developed into a commercially available laboratory test, which is now widely available both in clinical laboratories and in kit form for performance in physicians' offices. Refinement of methodology, particularly appropriate threshold determination, continues as recently reveiwed elsewhere.[3]

This statement concerns the relative merits of skin tests and RASTs for routine diagnosis of specific allergens responsible for IgE-mediated diseases. By necessity, this is a complex statement because consideration of this subject must deal with the relation of these tests to the broad program for diagnosis and management of allergic diseases, selection and interpretation of the tests, proper performance of the tests, the relative advantages of each test, the relative cost of skin tests and RASTs for the same diagnostic information, and the potential for abuse of both tests.

The Executive Committee of The American Academy of Allergy and Immunology has taken the position that most physicians agree on certain basic principles with regard to the care of patients with allergic diseases that are outlined in paragraphs A to E.[4,5]

A. Patients with allergic diseases are numerous, sick, need medical care, and of necessity will contract for medical care for these diseases.

B. Physicians who provide medical care for patients with allergic diseases should be properly trained, should maintain their training, and should expend considerable skill, effort, and time in order to provide adequate services to allergic patients. They should be compensated fairly for these necessary and properly performed services. Proper management of the allergic patient should include the following.

   1. Thorough history, physical examination, and appropriate laboratory procedures including skin tests and, where appropriate, RASTs to identify the factors provoking the allergic and any concomitant diseases are necessary.
   2. Training the patient (and his or her family) in procedures for the amelioration and/or elimination of the many factors that provoke allergic diseases that include at least exposure to allergens, tobacco, and other inhaled irritants, emotional tension, infection, climate factors, obesity, and exercise is important.
   3. Concomitant diseases such as diabetes and hypertension must be properly controlled, and their management must be put in proper perspective in the patient's overall program for medical care.
   4. Medication for control of symptoms of allergic diseases will frequently be needed despite the care outlined in paragraphs 2, 3, and 5 and will include antihistamines, corticosteroids, bronchodilators, and other drugs. This medication should be carefully supervised and adjusted to the patient's needs.
   5. Appropriate immunotherapy should be given when indicated and should be properly supervised by the allergist either in his or her office or elsewhere.

An individualized and often complex program is essential to provide good long-term medical care for the total patient. This will often involve both the patient and his family. It is important to emphasize that such a program demands a broad approach and the use of multiple procedures. Physician training programs, physicians providing care, and insurance programs should insist on such an integrated broad approach.

C. Private and/or national health insurance should provide proper benefits for the patient with allergic diseases.

D. Physicians must guard against the injudicious use of skin tests and RASTs. Indications for testing should be clearly documented in the patient's record.[4]

E. The Executive Committee of The American Academy of Allergy and Immunology has expressed concern about the use of the results of allergy skin tests or in vitro assays of specific IgE antibodies as the sole basis for formulating allergenic extracts for immuno-therapy. Such practice has often been conducted by physicians who have not had direct personal contact with the patient and by allergenic extract suppliers.

The Executive Committee has stated that it strongly believes that good medical practice is best conducted by physicians, including allergists, who personally perform or supervise the history and physical examination, which are the fundamental investigative procedures, and who personally supervise further diagnostic and therapeutic procedures.

The validity of laboratory procedures that may be useful in investigating possible allergic disorders, such as allergy skin tests and RASTs, is based not only upon the proper technical performance of these tests but also on their clinical interpretation and on the choice of appropriate tests. The necessity for evaluating the results of such tests within the context of the detailed historic information and the patient's physical status cannot be overemphasized. Consequently, the indirect or remote direction of allergy investigation or therapy of the type described in paragraph E_1 is not in the interest of good patient care and should be strongly discouraged.[5]

F. With reference to the comparative merits of skin tests and RASTs for routine diagnosis of specific allergens responsible for IgE-mediated disease, the following statements are considered to be basically correct at this time:

   1. Optimally performed skin tests and RASTs both detect IgE antibody accurately and reproducibly.[3,6,7]
   2. Within the constrainsts of each method, both skin tests and RASTs yield information of a semiquantitative nature, but RASTs are less sensitive than skin tests.[6]
   3. Results of both tests usually correlate equally well with allergic symptoms and signs produced by exposure to the specific allergen tested.[3,6,7]
   4. Both tests can be used as grounds for instituting immunotherapy in an efficient and economic manner. Where RAST is used as grounds for immunotherapy, a skin test with the planned initial dilution of immunotherapy solution should be done before starting immunotherapy to prove that the patient tolerates in vivo administration of this allergenic extract.[3,7]
   5. Skin tests appear to be superior to currently available RASTs in the diagnosis of certain life-threatening anaphylactic states in which maximum sensitivity is important, particularly in the diagnosis of penicillin and Hymenoptera allergy.[6]
   6. The results of skin tests are more immediately available. Where both tests can be initiated at the time of the patient's visit, the results of skin tests are available in about 45 min; those of RASTs are available in 2 to 3 days.[8]
   7. RAST is preferable to skin testing in certain conditions where skin testing is unsatisfactory, particularly where there is dermatographia or widespread skin disease.[8]

G. Skin tests are usually most cost effective than RASTs. Based on skin test and RAST charges from sources participating in the analysis, RASTs cost from two to six times more than skin tests per allergen tested.[9]

H. Abuse of skin testing and RAST is of great concern to allergy patients, practitioners, and insurance companies. Some recognized abuses are listed below:
   1. Commercial availability of extracts of substances that are not proved allergens and use of these for skin tests and RASTs.[6] Some commercial laboratories have marketed RASTs for substances not proved to be allergenic, such as aspirin, radiocontrast dyes, and codeine. Such tests can be highly misleading and a source of unnecessary expense.
   2. Poor quality control of potentially proper skin tests and RASTs in physicians' offices.[6] This abuse is often caused by poorly trained or inexperienced personnel.
   3. Poor quality control of RAST and use of unorthodox procedures exist in some commercial laboratories.[6]
   4. Irresponsible promotional techniques may be used:
      a. By commercial firms who sell equipment for RAST testing in physicians' offices by emphasizing the profit motive rather than the cost/benefit ratio of skin testing and RAST.
      b. By individual physicians who misrepresent the value of skin testing and RAST and urge patients to accept tests in inappropriate clinical circumstances (e.g., RAST for patients already shown to have negative reactions to appropriate and more sensitive skin tests).
   5. Inappropriate selection and interpretation of skin tests and RASTs with reference to the results of history and physical examination.[6] This abuse often takes the form of using routinely a large battery of tests that include tests for many allergens that are not present in the home, work area, or geographic locality of the patient and tests that experienced allergists would consider irrelevant and a source of needless expense.

I. Abuses can be minimized by the following measures:
   1. Increasing regulatory control over allergenic extracts used for skin tests and RASTs so that extracts are not licensed for sale unless proved to be effective for diagnosis and of specified potency: The Executive Committee of The American Academy of Allergy and Immunology has recommended that preparation, determination of biologic potency, labeling, storage, dilution, and shipment of allergenic extracts conform to currently acceptable standards that will ensure acceptable potency when the extract is used.[10]
   2. The Federal Government Center for Disease Control, the Health and Human Services Department, and some professional medical organizations have programs for monitoring quality control in a number of clinical pathology laboratories. The Executive Committee of the American Academy of Allergy and Immunology has recommended that similar monitoring of tests for specific IgE (such as RAST) done in commercial laboratories be encouraged.[8]
   3. Physicians and patients must be informed and trained with reference to proper procedures and quality controls for skin testing and RAST and with reference to costs and realistic benefits to be expected from each.[4,6]
   4. Rational and consistent policies of insurance carriers with regard to reimbursement for diagnostic tests used for the evaluation of patients with allergic diseases that encourage the use of the most cost-effective procedures are to be established. For instance, consider reimbursement ceilings or "caps" applicable to both skin tests and RASTs to discourage abuse, provide incentive for the more cost-effective procedure when possible, and assure fairness to patients suffering from allergic diseases.

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*From the Practice Standards Committee. The American Academy of Allergy and Immunology; reviewed and revised March 1983.

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PAY MORE ATTENTION TO WHOM?

To the Editor: To teach medical students respect for the hallowed humanitarian traditions of our profession is a noble enterprise. However, telling medical students to "pay more attention to their patients and less to themselves"[1] may lead to serious personal problems in the future lives of these young doctors.

It seems to me that most doctors *do* pay more attention to their patients than to themselves. This means that they also pay less attention to their families and to their friends. This may account in part, for the high rate of suicide and alcoholism in our profession.

It seems right that if we are going to stress the importance of caring for patients to medical students we should also teach them the importance of caring for themselves.

Edward J. Volpintesta, M.D.
Bethel, CT.

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[1] Massey RU: Reflections from the dean's office: marketable skills or an education? Connecticut Medicine 48:267, Apr 1984.

1984 CSMS ANNUAL MEETING HIGHLIGHTS

Joseph S. Sadowski, M.D., of Hartford, right, accepts the president's gavel plaque as the newly installed President of the Society from Daniel W. Doctor, M.D., of Westport, immediate past president.

Thomas R. Berglund, M.D., of Kalamazoo, Michigan, Secretary. Board of Directors, American Political Action Committee, addresses the CSMS House of Delegates with comments regarding AMPAC activities.

Daniel W. Doctor, M.D., of Westport, left, accepts a pin and bowl as the immediate past president of CSMS from Mehdi S. Eslami, M.D., of Waterbury, Vice-Chairman of the Council.

Howard Levitin, M.D., Dean of Students, Yale University School of Medicine, second from right, accepts a AMA-ERF check from Dr. Doctor, CSMS President, left, to aid needy medical students. Also participating in the presentations were Mrs. Charlotte Sandler, President of the Auxiliary to the Society, and Fritz Hinz, M.D., Associate Dean for Academic Affairs, University of Connecticut School of Medicine, who also accepted a check.

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SUMMARY OF PROCEEDINGS
HOUSE OF DELEGATES—ANNUAL MEETING
Hartford, Connecticut—May 9, 1984

Reports and Addresses

The House received reports, addresses and/or remarks from the President, Secretary, Treasurer, the Council, Delegates to AMA, Chairman of the Board of Directors of COMPAC, the Executive Director, the President of the Auxiliary to CSMS, Standing Committees, Representatives and Advisors, and the delegates from Massachusetts, New Jersey, New York, Vermont and Rhode Island. In addition, Thomas R. Berglund, M.D. of Kalamazoo, Michigan, Secretary of the Board of Directors of AMPAC, gave a verbal report on AMPAC activities.

Election of Officers and Others

The House voted to approve the published report of the Nominating Committee (the Council) with minor amendments. Officers elected were:

President: Joseph S. Sadowski, M.D., Hartford
President-Elect: William A. Whalen, Jr., M.D., Willimantic
Vice-President: Joseph C. Czarsty, M.D., Oakville
Secretary: Norman A. Zlotsky, M.D., Rockville
Treasurer: John J. Mendillo, M.D., New Haven
Speaker of the House of Delegates:
  Lawrence B. Ahrens, M.D., Wethersfield
Vice-Speaker of the House of Delegates:
  Mehdi S. Eslami, M.D., Waterbury
Three Delegates and Three Alternates to the AMA for the terms Jan. 85 Dec. 31, 86:
  Guy W. Van Syckle, M.D., Danbury (D)
  W. Raymond James, M.D., Essex (A)
  Frank K. Abbot, M.D., Hartford (D)
  Jerome K. Freedman, M.D., New Haven (A)
  Stewart J. Petrie, M.D., Derby (D)
  Andrew J. Canzonetti, M.D., New Britain (A)
  Edward A. Kamens, M.D., Fairfield (D)
  1/1/84-12/31/85
  Isadore H. Friedberg, M.D., Newington (A)
Councilor-At-Large 1/1/84-12/31/85
  Daniel W. Doctor, M.D., Westport

Presentations and Awards

Presentation to Retiring President: In recognition of his efforts as President of the Society during 1983-1984, Daniel W. Doctor, M.D., Westport, was presented with an inscribed silver bowl and a past president's pin. The presentations were made by Mehdi S. Eslami, M.D., Waterbury, Vice-Chairman of the Council.

Presentation to Incoming President: Following his inauguration, a plaque with a gavel, symbolic of the office of President of the Society, was presented to Joseph S. Sadowski, M.D., Hartford, by the retiring President, Daniel W. Doctor, M.D., Westport. Following the presentation, Dr. Sadowski gave his inaugural address, which placed emphasis on the need for physicians to become more involved in the political spectrum.

AMA-ERF Grants to Medical Schools: Provided by the AMA Education and Research Foundation, grants were awarded as follows: To the Yale University School of Medicine-$3,225.15. Accepting for Yale was Howard Levitin, M.D., Dean of Students. To the University of Connecticut School of Medicine--$1,957.56. Accepting for UConn was Fritz Hinz, M.D., Associate Dean for Academic Affairs.

Summary of Actions Taken

All items of business not calling for specific action by the House were accepted directly for filing. Items calling for action to be taken by the House of Delegates were heard by reference committees and based on the reports of the reference committees, were acted on as follows:

Mandatory Assignment

RESOLVED: That the Connecticut State Medical Society oppose any legislation requiring acceptance of medicare assignment as a condition for medical staff privileges.

Voluntary Physician Freeze of Fees for One Year

RESOLVED: That the Connecticut State Medical Society is concerned about the provision of cost effective medical care and, therefore, endorses the decision of the Board of Trustees of the American Medical Association to send a letter to each physician in the United States urging him/her to freeze fees for a one year period beginning immediately, and to continue to take into account the financial circumstances of each of his/her patients, especially the unemployed, the uninsured and those under Medicare and to accept reduced fees where and when warranted.

All Payers Legislation

The House of Delegates voted to recommend to the Council that it instruct the appropriate committee(s) to institute monitoring of the effects of the bill on the quality of patient care.

Infection Control in Long Term Facilities

RESOLVED: That CSMS recommend to the Department of Health Services, which licenses such facilities, that guidelines for implementing infection control policy in Long Term Care Facilities be adopted on a statewide level and that a continuing program for education in infection control be instituted on a regional basis.

Licensing of Physicians

RESOLVED: That the CSMS President assign a committee to evaluate and report on:

1. The present methods for physician licensure in Connecticut.
2. The credentialling process utilized by hospitals in Connecticut.
3. The present method of communicating among the states, the status of individuals practicing medicine, with or without a license, in or outside a hospital.

Physician Reimbursement for In-Hospital Care of Patients Prospective Pricing Systems Fee Schedules for Physicians

Three separate resolutions were introduced on the above subjects and the following resolution encompassing all three items was adopted:

RESOLVED: That the President of the CSMS appoint an Ad Hoc Commmittee to study and report to the House of Delegates by November 1984 on:

1. The types of reimbursement and payment systems being considered.
2. The impact of these systems on the availability and quality of patient care in Connecticut.
3. The ethical, moral and financial implications of these systems.
4. The alternatives open to the profession in coping with or opposing these systems, including legislative action, and be it further

RESOLVED: That the CSMS oppose legislation linking hospital and physician reimbursement, and be it further

RESOLVED: That the CSMS Council develop strat egies to oppose all-payer prospective reimbursement legislation requiring mandatory acceptance of fee schedules for physicians' services.

IN MEMORIAM

ANTELL, MAXWELL, University of Vermont, 1929. Dr. Antell was an internist in the Bridgeport area for 50 years until his retirement 12 years ago. He was a U.S. Army veteran of World War II and served in the South Pacific. Dr. Antell was affiliated with Park City Hospital, Bridgeport Hospital, and St. Vincent's Medical Center, where he was editor-in-chief of St. Vincent's Hospital bulletin. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died May 14, 1984 at the age of 80.

CASTAGNO, ROWE A., Columbia University College, Physicians and Surgeons, 1941. Dr. Castagno was an internist in the Hartford area since 1949. He served with the Army Medical Corps as a battalion surgeon in the European Theater during World War II. Dr. Castagno served on the staff of Hartford Hospital and was an internal medicine consultant for the Yearbook of Cancer. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died May 4, 1984 at the age of 69.

DEKLYN, WARD B., Temple University, 1941. Dr. Deklyn was a general practitioner and general surgeon in the Fairfield County area since 1942. Soon after, he entered the Army Medicap Corps as a surgeon. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died April 8, 1984 at the age of 67.

FOWLER, GEORGE A., Columbia University, 1940. Dr. Fowler was a general surgeon in the Litchfield County area since 1947. Before his retirement in 1976, he was a member of the surgical staff of Sharon Hospital. He was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died April 21, 1984 at the age of 70.

HERMAN, RALPH S., University of Buffalo, 1946. Dr. Herman was an internist in the Hartford area since 1950. He was a member of the staff of Hartford Hospital and Manchester Memorial Hospital and was chief medical consultant to the Connecticut Division of Rehabilitation until his retirement in 1976. Dr. Herman served in the U.S. Army during World War II where he was chief medical officer of Fort Williams, Maine. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died May 13, 1984 at the age of 51.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Connecticut – Emergency physicians and primary care specialists needed for busy freestanding emergency centers located in Connecticut. Attractive salary and fringes plus early ownership. Send CV to Box 1142, Farmington, CT 06034.

FAMILY PRACTICE

Family Practitioner, Board Certified or Eligible wanted for growing practice in Central Connecticut with one other Board Certified Family Physician leading to partnership. Send Curriculum Vitae to CSMS, FP/JR.

MISCELLANEOUS

HOSPICE PHYSICIAN. Position available after June 1, 1984, to be part of the medical staff of the nation's first hospice. The Connecticut Hospice is a JCAH accredited hospital with a 44 bed inpatient facility and a hospice based home care program of 50 patients. Excellent opportunity for a physician interested in palliative care. Connecticut license required. Board Certification preferred. Full-time position but part-time applicants may be considered. Please send C.V. to John M. Stober, Director of Human Resources. The Connecticut Hospice, Inc., 61 Burban Drive, Branford, CT 06405. An equal opportunity employer.

CONNECTICUT MEDICAL DIRECTOR – MEDICAID. The State of Connecticut Department of Income Maintenance seeks a physician to advise on the Medical aspects of policies, standards and procedures of the Medicaid Program and administer the Medical Services of the Department. Qualified Candidates must have completed a residency in an AMA-approved hospital and five years employment as a member of the medical staff of an institution offering generalized Medical care or as a practicing physician. Salary range: $48,299-55,966/yr. Please send resumes to: Donna Dickson, Agency Personnel Administrator, Department of Income Maintenance, 110 Bartholomew Ave., Hartford, CT 06106.

Physician has office space available in the vicinity of The Hospital of St. Raphael, New Haven. For further information call 777-5478.

PART TIME

Wanted: Physicians to work part time in clinic in New Haven area (evenings or weekends). Send c.v. and availability to CSMS, PT/CRR.

PRACTICE FOR SALE

Retiring physician has pediatric practice for sale to board eligible or certified applicant. Central Connecticut, close to medical center. Excellent coverage. Will introduce. Send CV, etc. to CSMS, PRAC/DDP.

A private medical practice in the town of Easton, CT is presently for sale. Suitable candidates would be either a general internist or family practitioner. Inquiries should be made to: Pasquale E. Perillie, M.D., Chairman, Department of Medicine, Bridgeport Hospital, 267 Grant Street, Bridgeport, Ct. 06602 (203) 384-3470.

Thriving family practice for sale in Southeastern Connecticut, 30 minutes from ocean, 90 minutes from Boston, 3 hours from Manhattan. Owner retiring but will introduce. Priced to sell. Very generous terms. Write Box 583C, West Springfield, MA 01090 or call (413) 536-5790 mornings or evenings after 9 PM.

PSYCHIATRY

Innovative, energetic, board certified or eligible psychiatrist desired for this attractive community of 40,000 in Central Connecticut. Economic package offered to help physician establish private practice. Please send C.V. to President, Bradley Memorial Hospital, 81 Meriden Ave., Southington, CT 06489.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

ALLERGY

May '84. Age 72. Nat'l bds. AB elig. MD, NY Medical College; Int., Middlesex Memorial Hospital; Res., Institute of Allergies, Roosevelt Hospital. Prefers General Practice, associate or industrial type practice. Available six months out of the year. Contact, Henry Sherwood, M.D., 210 Nehanton St., Apt. 114, Newton, MA 02159.

ANESTHESIOLOGY

January 1985. Licensed in Connecticut. Age 36. FLEX. AB elig. MD, Ein-shams Univ. School of Medicine, Cairo, Egypt; Int., Jersey City Medical Center, NJ; Res., Newark Beth Israel Medical Center, Newark, NJ; Res., Cambridge City Hospital, Cambridge, MA. Prefers solo, group, associate or institutional type practice in a small community. Write, Helmy W. Habek, M.D., 175 Adams St., Apt. 33, Newton, MA 02158.

FAMILY PRACTICE

Oct. '84. Licensed in Connecticut. Presently in practice. Age 48. Nat'l bds. MD, Columbia; Int., Medical College of Virginia; Res., Hartford Hospital; Fellowship, Adolescent Medicine, Children's Hospital, Boston. Desires group practice in a small-sized community. Also would consider Emergency Medicine. Write CSMS, TRA/FP.

FAMILY PRACTICE/PUBLIC HEALTH

Sept. '84. Age 36. FLEX. AB elig. MD, University of Pavia, Pavia, Italy; Int., McGill University, Montreal, Quebec, Canada; Res., Laval University, Quebec City, Quebec and John Hopkins, Baltimore, MD (Public Health). Prefers group, associate, institutional, solo, industrial and academic/research/administrator type practices in a medium-sized community. Write Gabriel Sella, M.D., 320 Niska Rd., Apt. 712, Downsview, Ontario, M3N 2W1, Canada.

INTERNAL MEDICINE

July '84. Age 30. AB elig. MD, M.R. Medical College, India; Int., S.S.G. Hospital, Baroda, India; Res., Bronx-Lebanon Hospital, Bronx, NY. Prefers group, associate or institutional type practice in a medium to large-sized community. Write, Gopal Shah, M.D., 100 Caton Ave., #2G, Brooklyn, NY 11218.

July '84. Licensed in Connecticut. Age 38. FLEX. AB elig. MD, St. George's University, Grenada, West Indies; Int., Bronx-Lebanon Hospital, Bronx, NY; Res., Mt. Sinai Hospital, Hartford, CT. Prefers any type practice. Write, T. Hemmaplardh, M.D., Apt. 1-H, Lathrop Lane, Rocky Hill, CT 06067.

Aug. '84. Age 35. Nat'l bds. AB cert. MD, Medical College of Pennsylvania; Int., Hahnemann Medical College and Hospital; Res., Long Island Jewish Hospital; Fellowship, Nassau County Medical Center and Joslin Diabetes Center. Is seeking an association with an internist/endocrinologist in a large-sized community. Training and subspecialty in pedi-endocrinology and adult diabetes. Write, Constance Stewart, M.D., 99 Pond Ave., D215, Brookline, MA 02146.

GASTROENTEROLOGY. July '84. Age 33. Nat'l bds. AB cert. (ABIM). MD, NY Medical College, Valhalla, NY; Int., Metropolitan Hospital, NY; Res., Metropolitan Hospital and Mount Sinai Services-City Hospital Center; Fellowship, Mount Sinai Services-City Hospital Center, Elmhurst, NY. Desires solo, group or associate type practice in a medium to large-sized community. Write, Neil Tarkin, M.D., 6700 192 St., Fresh Meadows, NY 11365.

Three months notice. Presently in practice. Age 33. Nat'l bds. AB elig. MD, Rush Medical College, Chicago, IL; Int. and Res., Nassau County Medical Center, NY. Prefers group, associate or HMO practice. Write, David R. Carnow, M.D., 3165 Kenwood Lane, Levittown, NY 11756.

CARDIOLOGY. Presently in practice. Aug. '84. Age 36. FLEX. AB elig. MD, Mysore Medical College, India; Int., North General Hospital, NY; Res., Wayne State University, Detroit and North General Hospital, NY; Fellowship, Downstate Medical Center, Brooklyn, NY and Newark Beth Israel Medical Center, Newark, NY. Desires solo, group, associate or institutional type practice in a small to medium-sized community. Prefers Invasive and Non-invasive Cardiology but will do Internal Medicine. Write, Nandakumar S. Iyengar, M.D., 52 Indian Run, Millington, NJ 07946.

OBSTETRICS/GYNECOLOGY

Immediately available. Age 37. FLEX. AB elig. MB, Topiwala National Medical College, Bombay, India; Res., Long Island College Hospital, New York; Fellowship, Michael Reese Hospital, Chicago, IL (Reproductive Endocrinology/Infertility). Prefers group, associate, institutional or partnership type practice in a medium to large-sized community. Write, Atul Sheth, M.D., 2951 King Dr., Chicago, IL 60616.

OTOLARYNGOLOGY

Aug. '84. Presently in practice. Age 53. FLEX. FRCS. (England). MD, Grant Medical College, Bombay, India; Int., J. J. Group of Hospitals, Bombay; Res., New York Hospital–Cornell Medical Center, NY; Fellowship, NY Eye & Ear Infirmary, NY. Prefers solo practice in a minimum drawing area of 50,000 population. Write, BDP/OTO.

PEDIATRICS

July '84. Licensed in Connectiuct. Presently in practice. Age 31. Nat'l bds. AB cert. MD, Johns Hopkins; Int., Georgetown University Hospital; Res., University of Maryland Hospital and Roosevelt Hospital. Desires primary care pediatric practice, either group or partnership. Also, any non-clinical opportunities. Write, CSMS, PED/SI.

July '84. Age 31. FLEX. M.B.B.S. and Int., University of Jabalpur, Medical College, Jabalpur, M.P., India; Res., Victoria Hospital, Jabalpur, M.P., India, Clara Swain Hospital, Bareilly, U.P., India and Illinois Masonic Medical Center, Chicago, IL. Prefers group or associate type practice. Write, Satish Kumar Shrivastava, M.D., 856 West Nelson, Apt. #1506, Chicago, IL 60657.

PSYCHIATRY

Jan. '84. Age 61. Licensed in Connecticut. Nat'l bds. AB elig. MD, McGill University, Montreal; Int., Royal Victoria Hospital, Montreal; Res., Allan Memorial Institute, Montreal and Boston State Hospital, Boston; Fellowship, Worcester Youth Guidance Center and Alcohol Addiction, Massachusetts General Hospital, Boston, MA. Wishes institutional type practice and would consider research position (Pathology). Write, CSMS, JEM/PSY.

RADIOLOGY

NUCLEAR MEDICINE. Presently in practice. Immediately available. Age 38. Nat'l bds. AB cert. MD, Civil Hospital, Ahmedabad, India; Int., Long-Island Jewish-Hillside Medicine Center, NY; Res., St. Vincent's Hospital–NYU, NY (Radiology); Fellowship, VA Hospital, University at Birmingham, AL (Nuclear Medicine). Prefers solo, group, associate, institutional and industrial type practice. Write, Subhash S. Pujara, M.D., Route 3, Box 391B, Andalusia, AL 36420.

SURGERY

DIAGNOSTIC. Aug. '84. Age 43. Presently in practice. Nat'l bds. AB cert. MD, Hannemann Medical University, Philadelphia, PA; Int., Roosevelt Hospital, NY; Res., NYU-Bellevue Medical Center, NY; Fellowship, Brigham and Women's Hospital, Harvard Medical School, Boston, MA. Prefers group, assoc. or institutional type practice in a medium to large-sized community. Has had nine years of general radiology including angio, nuclear medicine and ultrasound. Write, Eugene S. Barasch, M.D., P.O. Box 58, Harvard, MA., 01451.

SURGERY

VASCULAR. July '84. Age 31. Nat'l bds. AB elig. MD, Mt. Sinai School of Medicine, NY; Int., Res., and Fellowship, Mt. Sinai Hospital, NY. Prefers group or associate type practice. Write, Charles M. Miller, M.D., 1763 Second Ave., Apt. 21L, New York, NY 10128.

SURGICAL ONCOLOGY. Summer '84. Presently in practice. Age 35. FLEX. AB cert. MD, Christian Medical College (University of Madras, Vellore, India); Int., New Jersey College of Medicine and Dentistry, Neward, NJ; Res., Creighton University, Omaha, NB; Fellowship, Ellis Fischel State Cancer Hospital, Columbia, MO. Prefers solo, group or associate type practice in a medium to large-sized community. Write, CSMS, RVP/SUR.

June '84. Age 51. Presently in practice. Nat'l bds. AB cert. MD, Jefferson Medical College; Int., Williamsport General Hospital; Res., University of Miami and the University of NY at Buffalo. Prefers solo practice. Would like freedom to do a wide range of procedures including vascular and fracture work. Write, James M. Stern, M.D., 600 Vista Court, Waynesboro, PA 17268.

GENERAL/VASCULAR. August '84. Age 33. Nat'l bds. AB cert. MD, University of Puerto Rico; Int. and Res., S.U.N.Y. at StonyBrook; Fellowship, Lehigh Valley Medical Center. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Ruben J. Delgado, M.D., 7514 Oriental Trail, San Antonio, TX 78244.

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July '84. Age 36. Nat'l bds. AB elig. MD, Universidad Autonoma de Guadalajara, Guadalajara, Jalisco, Mexico; SUNY, Stony Brook, NY; Int., SUNY (General Surgery); Res., SUNY (General Surgery), Geisinger Medical Center, Danville, PA (Urology). Prefers solo, group, associate or institutional type practice. Write, Charles I. Sitomer, M.D., 300 Laura Dr., Danville, PA 17821.

Intravenous Digital Pulmonary Angiography for the Diagnosis of Pulmonary Embolism

ORTWIN RUSCH, M.D. AND NORMAN VINCENT, M.D.

ABSTRACT—Pulmonary digital subtraction angiography was performed from right atrial injection in 12 patients suspected of having pulmonary embolism when the lung scan interpretation was indeterminate or for clinical reasons in need of confirmation. Eleven diagnostic studies were obtained. The technique has been replacing the conventional transcardiac catheterization in most patients because of its easier performance and safety.

Introduction

The main appeal of digital subtraction angiography (DSA) is the venous approach as commonly used in the outpatient evaluation of carotid stenosis. By viewing an intravenous aortic arch study in real time substraction on the monitor, excellent opacification of the pulmonary arteries can also be seen, and not surprisingly this new technology, when applied to pulmonary angiography,[1-3] was found to be an acceptable substitute for the conventional examination in most patients with suspected major pulmonary embolism[4] (PE).

Often a clinically perplexing disease, PE remains a life-threatening complication of venous thrombosis in older bedridden patients unless anticoagulants are given, a treatment that has its own relatively high morbidity.[5] Recognizing PE, therefore, is as important as excluding the diagnosis which is best done with a normal perfusion lung scan.[6-7] The probability of having PE is determined by the combined use of ventilation/perfusion scanning and chest radiography according to interpretative guidelines that are generally, though not uniformly accepted.[7-8] The limited specificity of lung scans is expressed in the categories of moderate probability or indeterminate interpretation and calls for a direct demonstration of emboli. How often, then, is pulmonary angiography required?

In a recent prospective study,[8] 41% of 234 patients with clinical suspicion of PE had normal perfusion scans excluding the disease, and 15% had segmental or larger perfusion defects unmatched on the ventilation scan indicating a high probability of PE. In the remaining 44% of patients, the interpretation was indeterminate or neither sufficiently high nor low to confirm or exclude the presence of PE. If almost half of all patients undergoing lung scanning for the diagnosis of PE need confirmation by angiography, the introduction of intravenous pulmonary DSA as an easier, less expensive and safer examination[4] must clearly be welcomed.

Material and Method

During a four-month period in 1983, 155 patients had radionuclide lung imaging in this hospital for suspected PE. Pulmonary angiography was done at the discretion of the referring physician in 12 patients by intravenous digital subtraction technique and in two patients by conventional pulmonary arterial catheterization. One additional patient had pulmonary DSA as the primary examination when lung scanning was not available.

Xenon-133 ventilation images were obtained prior to perfusion imaging with Tc-99m MAA. Some patients had combined perfusion and Krypton-81m ventilation studies. A current chest x-ray was reviewed in all cases.

As digital subtraction unit, a Diasonics DF100 is interfaced with an existing fluorographic system in the angiographic suite.

The procedure was done percutaneously from an antecubital or femoral vein. Contrast material was injected in the right atrium. The field of view was selected according to areas of interest on prior lung scans in antero-posterior or oblique positions of the patient that best projected the pulmonary artery branches and minimized superimposition of cardiac motion. Mask mode subtraction was done by careful selection of a mask close to the image with the best opacification, and

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sometimes by shifting of the mask. Hard copies were made at optimal electronic contrast and brightness settings.

The diagnosis of PE was made by demonstrating arterial occlusion and filling defects. The clear opacification of segmental and subsegmental branches was used to exclude PE in that particular segment of the lung.

Results

Diagnostic DSA images were obtained in 11/12 (92%) patients. One patient had segmental perfusion defects in the left lower lobe and two DSA projections were equivocal in a segmental branch due to blurring by cardiac wall motion.

Pulmonary emboli were shown in two patients (Figure 1) who had a moderate to high probability of PE on lung scanning that needed confirmation due to gastrointestinal bleeding in one and coexisting lung cancer in the other patient.

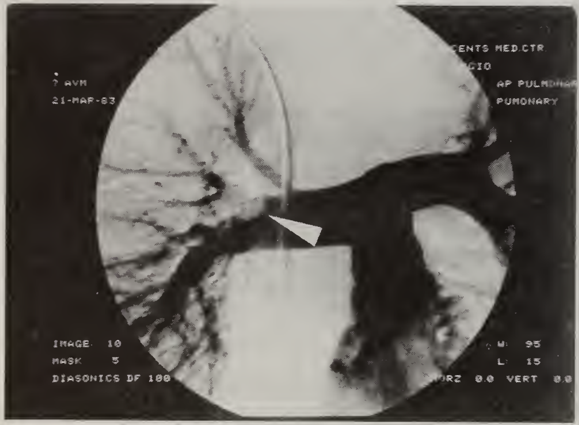

Figure 1
Legend: Intravenous pulmonary DSA demonstrating emboli by filling defects and occlusion of upper and middle lobe branches of the right pulmonary artery.

Patent segmental and subsegmental branches were demonstrated in nine patients with low probability or indeterminate interpretation in the presence of pleural effusion, atelectasis or consolidation of lung. The clinical follow-up in these patients revealed that anticoagulants either were not given or were discontinued, and treatment of other pulmonary or cardiac disease led to improvement and hospital discharge within two weeks. Pulmonary DSA without prior lung scanning was negative in one patient who later proved to have inflammatory pleuritis on biopsy.

The angiographic procedure was completed within 30 minutes after the patient was prepared, which included cardiac monitoring but no premedication. There were no serious complications. Three patients developed single premature ventricular contractions and one patient with congestive heart failure progressed into pulmonary edema which responded to therapy.

When lung imaging is normal, pulmonary embolism is virtually excluded. There is high probability of pulmonary embolism when two or more unmatched segmental perfusion defects are present, and low probability when perfusion defects are well matched by ventilation abnormalities. Patients whose lung images cannot be well categorized are considered indeterminate.

The majority of patients do not require pulmonary angiography, but there are several circumstances when angiography is recommended by the nuclear physician: First, indeterminate cases when lung imaging is of no diagnostic value but helpful in selecting the angiographic field. Second, whenever there is conflict between the clinician's and nuclear physician's assessment of the probability of PE. Also, there are patients with various combinations of COPD, congestive heart failure, lung cancer and post-radiation changes whose lung imaging would likely be indeterminate and who probably should go straight to angiography. Finally, angiography is desirable when anticoagulation would be of higher risk as in pericarditis or gastrointestinal bleeding.

A validation study of pulmonary DSA is provided by Pond, Ovitt and Capp[4] who performed the right atrial technique in conjunction with conventional pulmonary angiography and obtained an accuracy of 96.8% after excluding 6.1% of the digital studies for technical reasons. Small vessel resolution was found to be of better quality in selective injections but subsegmental branches were clearly demonstrated by DSA which was taken as our criterion of an adequate study.

Does it matter if smaller emboli are missed? The clinical course of 180 patients with suspected PE and negative conventional pulmonary angiogram revealed that none of the 167 untreated patients died of thromboembolic disease and none of the 147 surviving patients suffered recurrent embolism.[9] Hence, clinically significant PE was excluded by angiography which would also apply to pulmonary DSA if its accuracy stands up to the selective technique as reported.[2, 4]

In this study a common test indication was lung scanning rendered indeterminate by a very large pleural effusion or pneumonia which often cannot be differentiated from infarction. The angiogram excluded embolism despite the presence of a collapsed lobe surrounded by fluid, opacification of a lobe by pneumonia, or blood flow abnormalities in congestive heart failure. Pulmonary emboli were easily seen in two patients with moderate to high probability of PE on lung scan who needed confirmation for specific clinical reasons. Although small in number, this series of 12 examinations clearly showed pulmonary DSA to be useful in clinical decision making when lung scanning called for angiography.

During the same time interval two conventional pulmonary arteriograms were done by transcardiac catheterization, because the better small vessel resolution of selective injections was felt to be required. One patient with a high probability lung scan also needed an evaluation of pulmonary hypertension and left-to-right shunt, and the other patient with a low probability lung scan had a very high clinical suspicion of having PE. The angiograms were positive and negative respectively.

Patient motion and low cardiac output, which sometimes defeat carotid DSA, were in our experience no reason to switch to intra-arterial injections. Image sharpness is afforded by short exposure times, and adequate digital subtraction was achieved by selecting a mask closely preceding the arrival of contrast material. Image degradation by cardiac motion and by superimposed opacified structures was reduced by changing the patient's position, but nevertheless led to one non-diagnostic study. Cardiac gating which triggers the exposures in end-diastole may alleviate wall motion artefacts.[3]

The number of pulmonary angiograms has more than doubled in this hospital since the introduction of DSA, quite likely because it is easier and faster to perform, even in very distressed patients. The right atrial injection has the advantage of not exposing the patient to cardiac injuries and major arrhythmias that have been associated with 2.7% of transcardiac selective pulmonary angiograms in a large series.[10] It is important to remember, though, the rapid injection of ionic contrast material causes transient hemodynamic and electrocardiographic effects, that depend more on its concentration and volume than the site of injection.[11-12] Congestive heart failure may deteriorate as we have observed, and patients with pulmonary hypertension will poorly tolerate any further increase in pulmonary artery pressure.[10-11] It would probably be better in these cases selectively to inject less concentrated contrast material as permitted by the digital subtraction technique.

Pulmonary DSA from right atrial contrast injections has been well accepted in this hospital in the diagnosis of pulmonary embolism when the lung scan interpretation is indeterminate or in need of confirmation for compelling clinical reasons. Because it is easier to perform than conventional pulmonary angiography, the examination has been more frequently considered before deciding on anticoagulation. Selective catheterization can provide hemodynamic data and better small vessel resolution but diagnostic studies are obtained by right atrial pulmonary DSA in most patients suspected of having pulmonary embolism.

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BEHIND THE FACE OF HYPERTENSION

New evidence for central control

The Abdominal Aortic Form of Takayasu's Arteritis in a Young Woman

PRAVEEN K. ROHATGI, M.D., ROBERT M. JERESATY, M.D.
AND DANIEL KAHN, M.D.

ABSTRACT—A young woman with the abdominal aortic form of Takayasu's arteritis is reported. This form which is often associated with hypertension and absent femoral pulses mimics coarctation. Our patient underwent bypass surgery from the ascending to the abdominal aorta.

Takayasu's arteritis is a chronic inflammatory arteriopathy of unknown etiology, mostly affecting young oriental women.

We hereby report the case of a young Indian woman who presented with hypertension and abdominal bruits and in whom the abdominal aortic form (Type II) of Takayasu's arteritis was documented.

Case Report

C.R. 27-year-old Indian secretary, with known history of hypertension the last two years, was admitted with complaints of bitemporal headaches, vague non-exertional pain and one episode of epistaxis. She also noticed cold feet, numbness and pain on walking and poor healing of minor injuries of the lower extremities. Her hypertension was well controlled on 50 mg. of Atenolol daily but the drug was discontinued a few days prior to her admission for cardiac catheterizaton. She had no significant past history or relevant family history.

On examination, she was a thin lady, pulse 84/min., BP 170/105 in the right arm and 160/100 in the left arm. The BP was not measurable in the lower extremities. Both femoral pulses were weak and delayed. There were no carotid bruit, and the carotid upstroke was brisk. The posterior tibial and dorsalis pedis were not palpable. Lungs were clear on auscultation. The heart was of normal size and no heaves or thrills were felt. The heart sounds were of normal quality and there was a Grade II/VI long, blowing systolic murmur heard at the apex and at the left lower stenal border. The murmur was not transmitted to the back. A loud abdominal systolic bruit was heard.

Sedimentation rate was 30 mm., serum creatinine was .8 and urinalysis was negative. ECG revealed no abnormalities. Chest roentgenogram was within normal limits. M-Mode echocardiogram was normal and 2D echocardiogram of the aortic arch obtained with the transducer placed above the suprasternal notch revealed no coarctation.

Cardiac catheterization: The catheter was advanced from the right brachial artery as far as the right common iliac artery and on pullback, the most distal pressure was 87/75 rising to 95/75 in the abdominal aorta and then to 145/74 in the thoracic aorta. Aortography showed normal ascending aorta, aortic knob and proximal descending aorta. The distal descending aorta narrowed gradually resembling a "rat tail." Two areas of significant stenosis were noted in the abdominal aorta, the first at the level of the celiac axis proximal to the renal arteries and the superior mesenteric artery, and the second distal to the renal arteries (Figures 1 and 2).

Bypass surgery was performed on 5/5/83 by Dr. E. Stanley Crawford at the Methodist Hospital in Houston, Texas. The surgery consisted of ascending aorta to juxtarenal aortic bypass utilizing tubular Dacron graft with side-to-side anastomosis at that level and then continuing the same tubular graft distally to the aorta just proximal to the bifurcation with an end-to-end anastomosis.

The Pathological examination of an abdominal aorta specimen (6 X 4 X 3 mm.) showed medial degeneration, fibro-intimal proliferation and adventitial fibrosis with no evidence of active aortitis.

The patient was taken off all medications postoperatively and has remained normotensive. She no longer has symptoms referred to her lower extremities. Blood pressure is now 120/70 in both arms and both femoral and postero-tibial pulses are 2 + and the pedal pulses are faint.

Discussion

The chronic inflammatory arteriopathy, first described by Savory[1] in 1856, has been known as Takayasu's arteritis since the author described in 1908[2] the peculiar changes in the central vessels of the retina. Later Shimizu and Sano defined the clinical features of this disorder and subsequently reports of this disorder have originated from various parts of the world: Japan, India,[3] Scandinavian countries, Mexico, South Africa.

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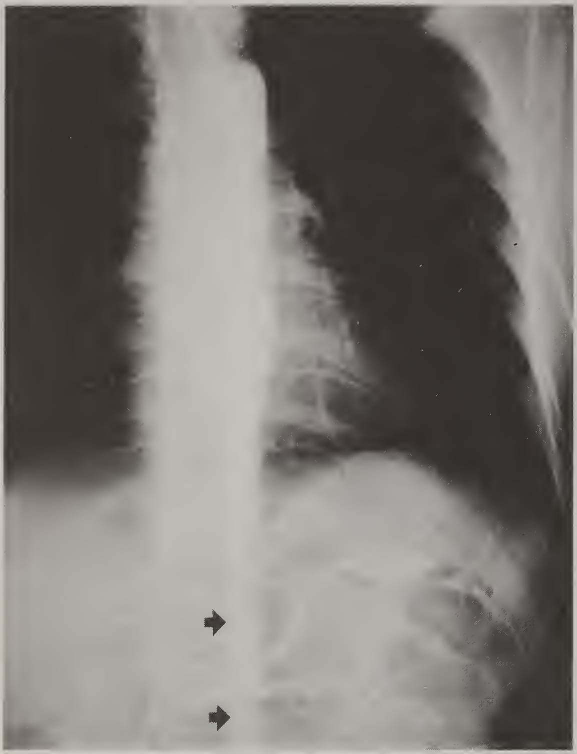

Figure 1
Thoracic and abdominal aortogram showing gradual narrowing of the descending and abdominal aorta ("rat tail sign") and two areas of stenosis of the abdominal aorta (arrows).

The first American report was published by Elliot, Ussher and Stone in 1938.[4]

One of the most important features of Takayasu's arteritis which distinguishes it from other forms of aortitis is the presence of "stenotic" lesions with or without dilatation of the blood vessels.[5] The basic pathology affects the intimal and medial layers of the aorta frequently presenting as Panaortitis. Although fibrotic thickening occurs in all layers, it is pronounced in the intima, resulting in stenosis.

The etiology of the disease remains obscure, but an autoimmune mechanism has been postulated and antiaorta antibodies have been described. In its classical form the aortitis has an early systemic phase (including fever, sweating, weight loss and arthralgia) and a late occlusive phase with regional ischemia.

Until 1962, there were three types of Takayasu's arteritis described.[6] In Type I, the involvement is localized to the aortic arch and its branches. In Type II, lesions involve the abdominal aorta and the descending thoracic aorta, and in Type III, the commonest, mixed features of the above two types are noted. In 1962, a Type IV involving the pulmonary artery was described. (Our case is a typical example of Type II.)

Although absent or diminished femoral pulses in hypertensive patients are usually indicative of coarctation, Takayasu's arteritis should be considered in the differential diagnosis, particularly in young oriental women. A triad consisting of thoracoabdominal bruit, diminished or absent femoral pulses, and lack of rib notching, are highly suggestive of congenital abdominal coarctation or Type II Takayasu's arteritis. The differential diagnosis is made by aortography which shows a typical "rat tail" appearance in Takayasu's arteritis. In order not to miss the "rat tail" appearance and the abdominal aortic involvement, total aortography should be performed.[7] Hypertension in Takayasu's arteritis should be controlled by drugs. Indications for surgical treatment include intractable hypertension with or without renovascular component, leg claudication and expanding aneurysm.

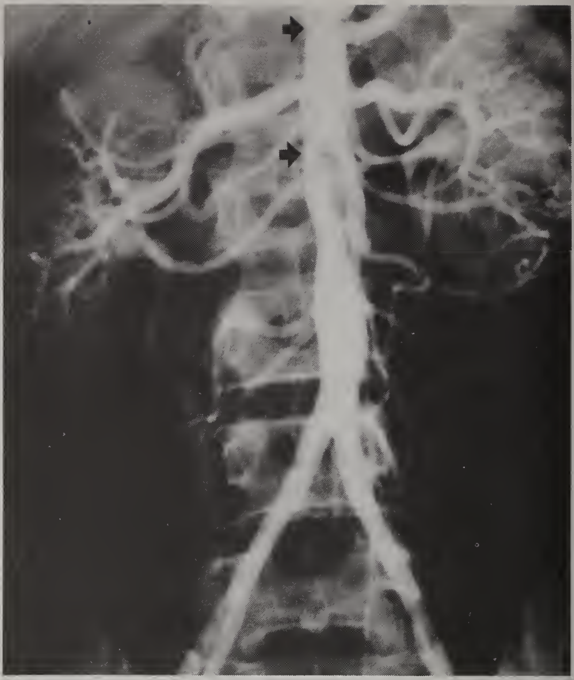

Figure 2
Abdominal aortogram showing two areas of stenosis (arrows) proximal and distal to the renal arteries.

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Acute and Delayed Side Effects of Definitive Pelvic Irradiation for Urologic Cancer

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ABSTRACT—95 patients treated radically by radiotherapy for carcinoma of the bladder or prostate have been followed for acute and delayed side effects. The acute side effects were generally mild and transient, improving in the majority of patients by 8 weeks following the completion of irradiation. For patients treated with external beam irradiation delayed complications occured in less than 10% and included persistent diarrhea 4.8%, proctitis 3.6%, hematuria, cystitis, and urethral stricture. The treatment factors contributing to a low complication rate are discussed.

Radiotherapy as curative treatment for patients with carcinoma of the bladder or prostate is a well accepted and widely practiced modality.[1-4] The staging procedures, techniques of treatment and irradiation doses employed, all differ between treating facilities and it is therefore difficult for the clinician to accurately predict the possible complications when radiotherapy is the recommended treatment.[5-12] Although previous reports have studied the delayed complications of pelvic irradiation,[5, 9, 11] little has been published on the incidence of acute side effects seen during such treatment. This paper reports the acute and delayed side effects of radical radiotherapy for patients treated in a uniform manner.

Methods and Materials

The radiation therapy charts and medical records of all patients treated at the Joint Radiation Oncology Program of St. Mary's Hospital and Waterbury Hospital for the 40 month period between June, 1979 and October, 1982 were reviewed. Those patient with primary bladder or prostate carcinoma treated radically were included. The only patients excluded were those treated with clearly palliative intent or those patients treated in an adjuvant fashion, either pre- or post-operatively. A total of 95 urologic cancer patients are included in this survey. Thirty-two patients with transitional cell carcinoma of the bladder were treated with a radical course of external beam irradiation. Sixty-three patients with adenocarcinoma of the prostate were treated radically, fifty-two with external beam pelvic irradiation, and eleven with radioactive ^{125}Iodine seed implantation.

All patients had a complete history and physical examination, chest X-ray, intravenous pyelogram, bone scan, CT scan of the pelvis, and complete blood count. Those patients with adenocarcinoma of the prostate also had a serum acid phosphatase determination. Prior to treatment, all patients had localization studies with contrast medium in the bladder and barium in the rectum. Until October, 1981, all patients were treated on an isocentric cobalt unit. Following this, the remainder of the patients were treated with a 4 MEV or 10 MEV linear accelerator. All patients were treated by the same two radiation oncologists. Treatments were delivered 5 days per week without any scheduled breaks in the treatment course. The prescribed dose for most patients was 4500 rads to the whole pelvis, using daily fractions of 180 rads, followed immediately by an additional 2000--2200 rads delivered to the primary tumor volume as indicated by pelvic CT scan using 180 or 200 rad daily fractions. For the initial 4500 rads to the whole pelvis, most patients were treated using a 4 field portal technique with appropriately shaped portals to minimize the dose to the surrounding small and large bowel if possible. Anterior and posterior pelvic portals averaged 15 cm in width by 17 cm in height. Lateral portals averaged 10 cm in width for patients with carcinoma of the prostate and 12 cm in width for patients with bladder carcinoma. Cone-down radiation portals to the primary tumor volume usually employed a partial arc rotation technique for prostatic carcinoma and a three field technique for bladder carcinoma. Computerized treatment planning was utilized for all patients.

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Patients selected for radioactive ^{125}Iodine seed implantation had single nodules confined to one lobe of the prostate (Stage BI), well-differentiated tumors, normal pelvic CT scans without evidence of extracapsular spread of the tumor, and no evidence of regional lymph node metastases at the time of lymph node dissection. An average of thirty-eight seeds were implanted in each patient, which delivered a calculated dose of 20,000 rads to the entire prostatic volume in all patients.

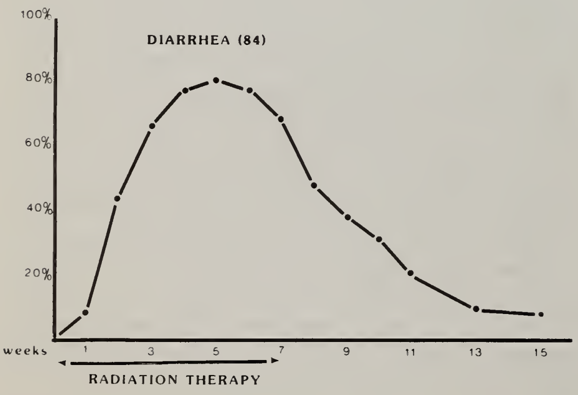
Results

The minimum follow-up for these patients was 1 year, with a maximum of 52 months (median 31 months). No patient was lost to follow-up. The average dose delivered to the whole pelvis in those patients receiving external beam irradiation was 4340 rads with an average cone-down dose to the tumor volume of 2190 rads for an average total tumor dose of 6530 rads.

Acute gastrointestinal side effects for all 84 patients undergoing external beam irradiation are listed in Table 1. Diarrhea requiring medication was the most common side effect seen in 80% of patients after 5 weeks of pelvic irradiation. The average radiation course took about 7 weeks and the incidence of diarrhea had decreased to 6% at 8 weeks following radiation therapy. (Fig. 1) Other acute GI side effects included hemorrhoidal inflammation 8.3%, rectal bleeding 3.6%, and weight loss (of greater than 5%) seen in 11.9% of patients.

Table 1

Acute GI Side Effects (84 Patients)			
Diarrhea	*80%*	@	5 weeks
	20%	@	11 weeks
	6%	@	15 weeks
Hemorrhoidal Inflammation	8.3%		
Rectal Bleeding	3.6%		
Weight Loss (5 + %)	11.9%		
Acute GU Side Effects (52 Patients)			
Dysuria	26.9%	@	7 weeks
Increased Urinary Frequency	21.2%	@	7 weeks
Increased Nocturia	5.8%	@	7 weeks
Hematuria	5.8%	@	3 weeks
Documented UTI	3.8%	@	4 weeks



Acute urologic side effects from pelvic irradiation were analyzed for those 52 patients undergoing external beam irradiation for prostate carcinoma. The patients with a primary diagnosis of bladder carcinoma were not included in this portion of the analysis since most of them had irritative urinary symptoms at the time of diagnosis. (Table 1) Dysuria was the most common acute urologic side effect seen in 26.9% of patients at the completion of radiation therapy. This had decreased to 5.8% at 8 weeks following completion of radiation therapy. (Figure 2) Other acute urologic side effects included increased urinary frequency seen in 21.2% of patients after 7 weeks of pelvic irradiation, increased nocturia in 5.8% at 7 weeks, hematuria in 5.8% after 3 weeks of pelvic irradiation, and documented urinary tract infections in 3.8% of patients after 4 weeks of treatment.

Complications following radiation therapy were termed delayed if they occurred 8 weeks or more following the completion of treatment. (Table 2) Delayed GI complications included persistent or intermittent diarrhea requiring medication seen in 4.8% of patients given external beam irradiation. Radiation proctitis usually accompanied by rectal bleeding was seen in 3.6% of patients treated with external beam irradiation and 18% of the patients treated with iodine seed implantation. No patient in our series suffered a small bowel injury following treatment. Complication rates from other published series are listed in Table 2 for comparison.

Delayed urologic complications are listed in Table 2. Hematuria was the most commonly encountered complication, seen in 9.6% of patients treated with external irradiation for prostate carcinoma. 28% of bladder cancer patients developed hematuria following radiation therapy, but many also developed tumor recurrence, and the true complication rate is therefore difficult to accurately assess. Radiation cystitis developed in 9.4% of bladder cancer patients and 1.9% of prostate cancer patients. Urethral stricture, although commonly reported in the medical literature (5-12%), was seen in only 1 patient.

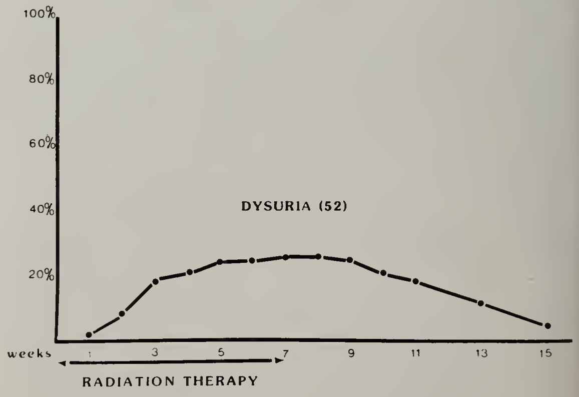


Table 2

Delayed GI Complications		(Waterbury)	(Published Series 2, 5, 9, 10)
Persistent Diarrhea	(4/84)	4.8%	3% - 9%
Proctitis with Bleeding XRT	(3/84)	3.6%	3% - 26%
125_I	(2/11)	18%	
Small Bowel Injury	(0/95)	0%	1% - 2%
Delayed GU Complications		(Waterbury)	(Published Series 2, 6, 9, 10, 11)
Hematuria			
Bladder	(9/32)	28%	
Prostate XRT	(5/52)	9.6%	2% - 14%
Prostate 125_I			
Prostate		0%	
Cystitis			
Bladder	(3/32)	9.4%	
Prostate XRT	(1/52)	1.9%	4% - 28%
125_I			
Prostate		0%	
Urethral Sticture			
Bladder		0%	
Prostate XRT	(1/52)	1.9%	5% - 12%
125_I			
Prostate		0%	
Symptomatic Subcutaneous Fibrosis		0%	2% - 8%
Impotence		?	6% - 31%
Leg Edema (Laparotomy)		0%	21% - 25%
(No Laparotomy)		0%	1% - 8%
Urinary Incontinence (TUR)		0%	4% - 13⅛
(No TUR)		0%	2% - 4%

Radiation induced impotence could not be estimated, since few patients had adequate detailed sexual histories recorded prior to treatment. No patient in our series developed symptomatic subcutaneous fibrosis, leg edema or urinary incontinence.

Discussion

Recognizing the predicted frequency of acute and delayed side effects of treatment aides in the correct diagnosis of such morbidity and its appropriate management. An accurate prediction of treatment morbidity may also assist the clinician in recommending a treatment modality (e.g. irradiation or surgery) when comparable control rates exist for a specific stage of malignancy.

In this series of patients given pelvic irradiation, the most common acute gastrointestinal side effect was diarrhea which was common, but transient and responded to diphenoxylate or loperamide. Interestingly, the incidence decreased prior to the completion of a 7 week course of pelvic irradiation, and this may reflect the smaller radiation portals used during the final 2 weeks of treatment. Following the end of pelvic irradiation, the incidence continued to decrease, eventually reaching a rate of less than 5%. The other acute side effects of hemorrhoidal inflammation, rectal bleeding and transient weight loss were much less common and were self-limited. The delayed complication of radiation proctitis occurred in only 3.6% of our patients treated with external beam pelvic irradiation and 18% of patients treated with ^{125}Iodine seed implantation. Small bowel injury, although reported by others[5-9] was not seen in this series.

In contrast to the gastrointestinal side effects, the acute urologic side effects tended to reach their peak incidence at the completion of a 7 week course of irradiation. This may be due to the inability to shield the prostatic urethra and much of the bladder mucosa during any part of external beam irradiation for treatment of either prostate or bladder carcinoma. Again, the symptoms were transient with the long term urologic complications of hematuria and cystitis occurring in less than 10% of patients treated for prostate carcinoma.

Leg edema, secondary to vascular and lymphatic damage by irradiation, was not seen in this series, probably due to the lack of routine staging laparotomies with lymph node dissection. Such dissections have resulted in leg edema for up to 25% of radiated patients in the Stanford and Washington University, St. Louis series.[1, 9]

Factors possibly responsible for the low incidence of complications in this series, are listed in Table 3. A 4 field portal technique maximizes the daily radiation dose to the treated volume (e.g. bladder or prostate plus

Table 3
FACTORS IN DECREASING COMPLICATIONS

4 Field Portal Technique
Shaped Portals
All Portals Treated Daily
180 Rads/Day
Distended Bladder if possible
Tumor localization with CT
Computerized Treatment Planning
High energy (10MeV) if available

pelvic lymph nodes) while limiting the daily dose to the posterior rectal wall and anterior small bowel. The use of shaped radiation portals also limits the daily dose to small bowel, soft tissues and the perineum. By treating all portals daily, the biologic effect is uniform for the tumor volume while consistently less for surrounding normal tissues. The use of 180 rad daily fractions for treatment of the whole pelvis is felt by others[8] to diminish the acute and delayed side effects of therapy and eliminates the radiobiologic uncertainties of stopping treatment for several weeks in the midst of therapy,[12] or altering the sequence of large and small field irradiation[1] when daily doses of 200 rads are employed. Distending the bladder during irradiation by forcing fluids prior to each treatment session, may diminish gastrointestinal toxicity by displacing a significant volume of small bowel out of the treated pelvis. The routine localization of prostate and bladder carcinomas by CT scan, has greatly assisted the radiation oncologist in appreciating the individual and frequently asymmetric volume of malignancy that must be adequately treated.[1, 8, 10] The use of computers for treatment planning allows the selection of the best geometric therapy plan for each patient utilizing individual beam sizes, angulation, orientation and rotation perimeters. Finally, the more penetrating radiation beams of high energy (10 MEV or greater) linear accelerators are ideal for treating deeply situated pelvic tumors while sparing more superficial soft tissues.

In summary, the use of a uniform treatment policy utilizing several important treatment factors, has resulted in a low rate of acute and delayed side effects for patients irradiated for carcinoma of the bladder or prostate. Side effects tend to be self-limited and, in general, tolerable and should therefore not dissuade the clinician from recommending such treatment for the appropriate patient.

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Differences Noted in Practices of Male and Female MDs

Women constitute a growing proportion of the medical profession and that proportion will continue to increase. From 1970 to 1981, the percentage of female physicians increased from 7.7% to 12.2%. Nearly 30% of today's medical students are women. A recent study by the AMA reveals that on the average, the number of patient visits each week and both annual and hourly income rates for female and male physicians differ. Career choice differences between male and female physicians were also noted in type of specialty, practice, and hours of work each week. While female physicians constituted 12.2% of all physicians in 1982, they comprised smaller percentages in general/family practice (8.9%) and surgery (5.6%), but larger percentages in medical and other specialties (15.4% and 15.1% respectively). Female physicians are less likely to be self-employed than men. One factor causing this difference may be that physicians 40 years of age or younger tend less frequently to be self-employed and a relatively larger proportion of women physicians are young. Female physicians averaged 7.9 fewer hours in practice each week than male physicians and saw an average of 18.5% fewer patients. The average annual net income for male physicians in 1982 was $102,000 compared to $65,200 for female physicians. When income per hour is calculated, women physicians earned $30.10 compared to $39.80 for men in 1982.

CT-Guided Stereotactic Neurosurgery

A Preliminary Report Using the Gouda Frame and Stereotactic System

JAMES K. SABSHIN, M.D., FRANKLIN ROBINSON, M.D., ISAAC GOODRICH, M.D.
AND ELIZABETH D. BROWNE, P.A., M.S.

ABSTRACT—Various CT-guided stereotactic systems have been developed recently for use in neurosurgical procedures. These systems allow low risk and highly accurate access to any point within the brain. The authors report their initial use of the Gouda frame and CT-guided stereotactic system and discuss the increasing importance and role for stereotactic approaches in neurosurgery.

Introduction

Recent advances in computerized tomography have stimulated a renaissance in stereotactic intracranial surgery. CT-guided stereotactic systems are available now for highly accurate (1-2 mm) and low risk access to any point within the brain.[1,3-6,8] These systems are proving useful in the diagnosis and treatment of CNS neoplasia (especially deep-seated lesions), movement disorders, seizures, infections, pain therapy and interstitial radiotherapy.

Historically, stereotactic neurosurgery defined as a method of inserting various instruments into precise 3-dimensionally localized target areas of the CNS, has its origin in the pioneer work of Sir Victor Horsley and R.H. Clark with their development of a stereotactic apparatus in 1908 for experimental primate surgery.[7] Neurosurgical stereotaxy was limited, however, in that era being based upon inconstant bony extra-cerebral landmarks. The more widespread use of stereotaxy in clinical neurosurgery awaited the development by Spiegel and Wycis in 1947 and others shortly thereafter of systems founded on more precise and constant pneumoencephalographic and other intracerebral landmarks.[9] The introduction of computerized tomography and its first stereotactic applications in neurosurgery by Bergstrom and Greitz in 1976 marked a further stage in stereotactic neurosurgery and led to the current development and broad application of various CT-guided systems.[2]

The authors have had considerable experience with some of these systems and with previous non-CT-guided devices, and have recently employed the Gouda frame which is a CT-guided stereotactic system. This paper reports our initial cases and experience with the Gouda frame system.

Gouda Frame and Stereotactic System

The Gouda frame and stereotactic system[4,5] are based on the principle of a movable arc with a target that is the center of a sphere with an infinite number of radii and is used in conjunction with the CT scanner (Figure 1) which allows precise target point selection on the appropriate CT scan slice. X and Y target point coordinates are generated on the CT screen from this selected slice. The Z or vertical axis coordinate is simply the distance from a selected zero CT plane on the frame to the target CT slice (Figure 2). The arc and frame system are adjusted to these precise X, Y and Z coordinates later during the procedure itself. Additional target points may be selected as indicated in cases such as multiple tumors, biopsies of different areas of a tumor, multiple abscesses, et cetera.

The procedure is begun with fixation of the reference frame to the patient's skull under local anesthesia with four sterile pins. Fixation of a reference frame to the skull, necessary in most CT-guided systems, is tolerated well by the patient. The CT scan is performed with the frame fixed in place and the appropriate target point for the procedure is selected. The X, Y and Z coordinates of the intracranial target are determined. The patient is then taken to the operating room with the reference frame in place for the planned stereotactic procedure.

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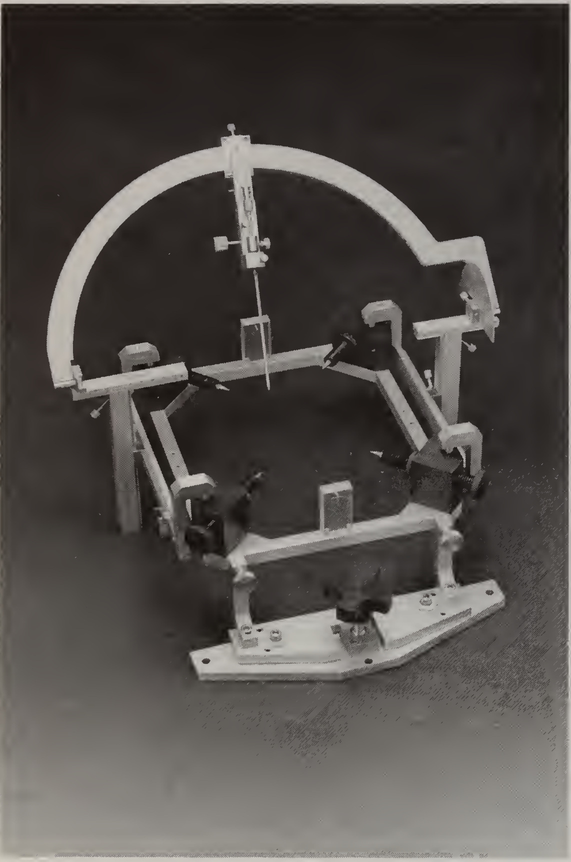

Figure 1
The Gouda frame and arc system.

Under sterile technique the arc is adjusted to the X, Y and Z coordinates and its accuracy double checked using a phantom target point device to which a biopsy probe is passed. The arc is then attached to the frame and a safe entry point is selected. Under local anesthesia with supplemental intravenous sedation, a single scalp incision and burr hole are made at the selected entry point. The frame is easily but firmly attached to the operating table with the patient in the supine position. The arc settings are checked and after a small incision is made in the dura, a biopsy needle or other instrumentation is passed to the selected target point. On completion of the procedure, the frame is removed, simple closure is performed, dressing applied and the patient is taken to the recovery room for observation.

The length of the entire procedure is generally less than two hours, including fifteen minutes for pin fixation, 30 minutes in the CT scanning unit and less than an hour for the surgical procedure itself. All procedures have been performed in the operating room given the need for sterility and the possibility of complications.

Case Reports

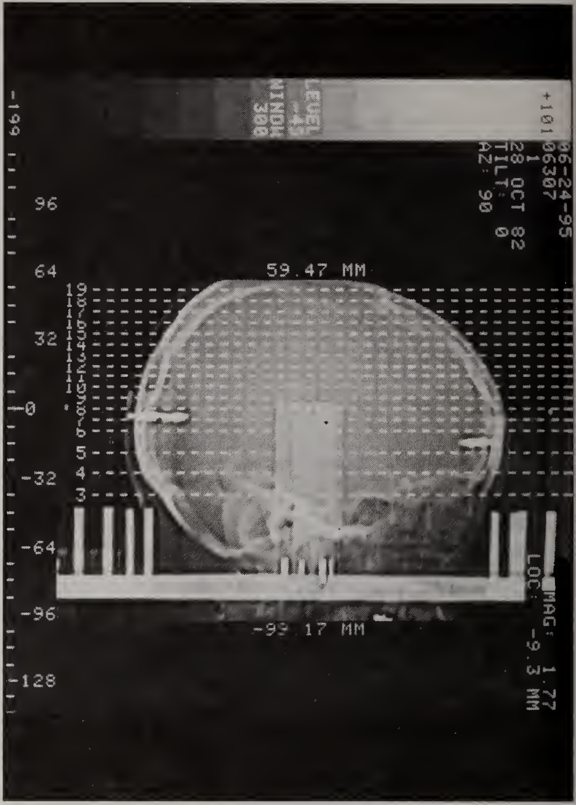

Figure 2
Scout views of skull with Gouda reference frame in place, showing various CT scan slices obtained.

Case #1. The patient was a 43-year-old female with a two month history of left-sided headaches and the subsequent development of focal seizures of the right upper extremity. CT scan of the head revealed multiple enhancing lesions of the left cerebral hemisphere with surrounding edema (Figure 3). There was a long history of poor dental hygiene and the question of multiple cerebral abscesses was raised. The patient was treated with Dilantin sodium and Decadron and also given a short preoperative course of broad spectrum antibiotics. Preoperative metastatic work up, including CXR, IVP, CT of the chest and abdomen, liver-spleen scan, bone scan and lumbar puncture, revealed no evidence of metastatic or infectious etiology. Using the Gouda frame system, a stereotactic biopsy was performed under local anesthesia. In addition to firm tissue specimens, some viscid, necrotic type material was aspirated and sent for bacterial (aerobic and anaerobic), fungal and AFB examination. Frozen sections were inconclusive. A red rubber catheter was then passed stereotactically and left in place for possible further drainage. Permanent pathology sections were consistent with glioblastoma multiforme. The catheter was removed and the patient subsequently underwent radiation therapy.

Case #2. The patient was a 55-year-old male with a one month history of increasing confusion and urinary incontinence. CT scan of the head demonstrated an enhancing mass deep in the right basal ganglia with surrounding edema and right to left shift (Figure 4). Cerebral angiography revealed the mass to be avascular. Appropriate metastatic workup was negative. The patient was treated with Dilantin sodium and Decadron. The Gouda frame system was used to perform a stereotactic biopsy of the deep-seated mass under local anesthesia. Permanent section of biopsy tissue revealed a Grade II astrocytoma. The patient's mental status continued to deteriorate. Radiation therapy was not believed indicated and he was transferred to a hospice.

Case #3. A 56-year-old male was initially seen for increasing confusion and the onset of left focal motor seizures. Examination revealed a left homonymous hemianopsia and mild left hemiparesis. CT scan of the head revealed an ill-defined right parietal mass lesion which did not clearly enhance. Cerebral angiography showed no significant tumor

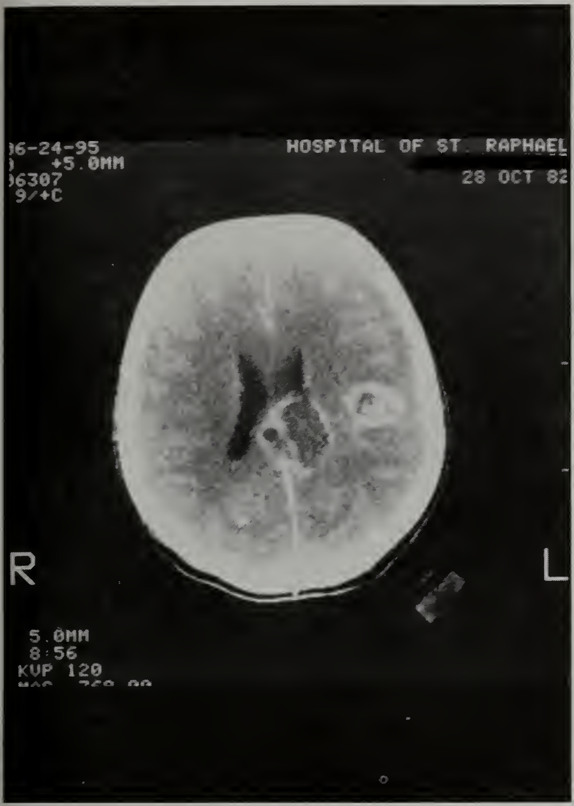

Figure 3
Case No. 1. CT scan showing multiple deep enhancing lesions of the left cerebral hemisphere.

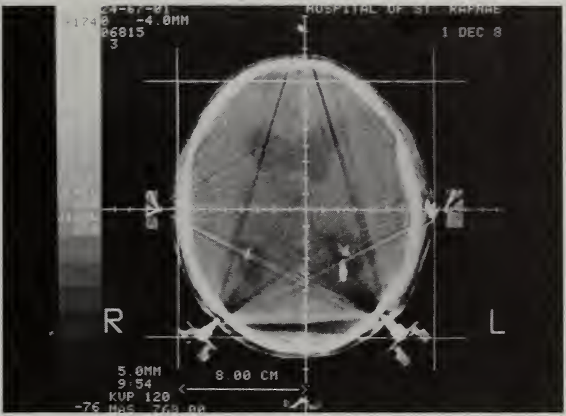

Figure 4
Case No. 2. CT scan showing deep right basal ganglia mass lesion and the X and Y coordinate grid as seen on the CT scan imaging screen which is used to select the target point.

vascularity. Appropriate preoperative metastatic workup was negative. The patient was treated with Dilantin sodium and Decadron and his confusion rapidly cleared and he had no further seizure activity. The patient initially was reluctant, however, to consider general anesthesia and craniotomy. The Gouda frame system was used to perform a stereotactic biopsy under local anesthesia. Permanent section was consistent with a glioblastoma multiforme. The patient subsequently underwent craniotomy under general anesthesia for tumor decompression followed by radiation therapy.

Discussion

These case reports represent our inital use of the Gouda frame system and have involved tumor biopsies. The first two cases demonstrate the accuracy of this system and its safety in the biopsy of tumors which are deep-seated and in critical areas of the brain. The third case demonstrates how CT-guided biopsies can increase surgical options and provide tissue for diagnosis in patients unwilling, at least initially, or medically unable to accept the risks of traditional general anesthesia and craniotomy. CT-guided stereotactic biopsy can allow safe and relatively easy differentiation between malignant and benign tumors in which a more favorable prognosis might obviously be obtained with tumor excision.

The Gouda frame has been used by others in various types of procedures including similar tumor biopsies.[4,5] Other systems based on similar CT-guided and fiducial principles are available but may require more elaborate CT or computer adjustments. CT-guided devices have been shown to significantly lower nondiagnostic biopsy rates and the incidence of complications such as intracerebral hematoma. The Gouda system is also compatible with NMR and PET scanning.

Future progress in neurosurgery will undoubtedly involve the earlier detection of CNS lesions and thus the potential role for precise stereotactic intervention will certainly increase. The future use of laser fiberoptic and endoscopic stereotactic instrumentation and use of stereotactic systems with NMR, PET, and ultrasound will also increase surgical options and improve results.

Acknowledgement

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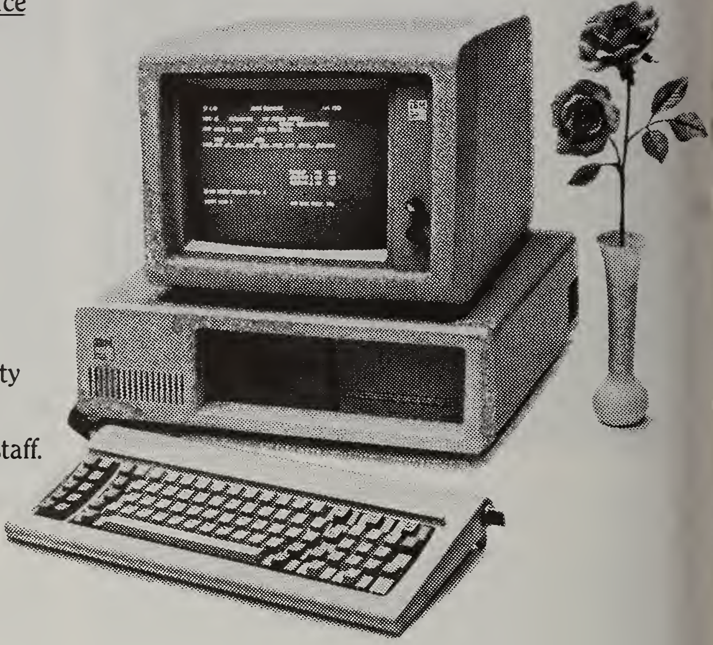

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Important Advances in Clinical Medicine

Epitomes of Progress—Anesthesiology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in anesthesiology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in anesthesiology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Anesthesiology of the California Medical Association and the summaries were prepared under its direction.

Outpatient Anesthesia Techniques: Continuous Intravenous Infusion of Anesthetic Agents

Outpatient surgical procedures have become increasingly popular because of savings in terms of both hospital beds and expenses. A long-standing contention of anesthesiologists has been that inhaled anesthetics (such as halothane and enflurane) are superior to intravenously given (IV) anesthetics for outpatient anesthesia because volatile agents are more controllable. Traditionally, IV anesthetics have been administered by intermittent bolus injections. By using continuous infusion techniques, anesthetists can more closely titrate these anesthetics to meet the changing needs of a patient during an operation. Recent studies of outpatients undergoing minor surgical procedures indicate that the continuous infusion of IV anesthetics (such as ketamine hydrochloride) and analgesics (such as fentanyl citrate) results in a 40% to 50% decrease in the drug dosage requirement and a significantly shorter recovery period when compared with the traditional intermittent bolus technique. After a standard thiopental sodium induction, a continuous infusion of fentanyl (5 to 10 μg per minute) or ketamine (2 to 5 mg per minute) was used to supplement nitrous oxide. Both fentanyl and ketamine were associated with intraoperative and postoperative problems. However, the new opioid analgesic, alfentanil hydrochloride, appears to offer significant clinical advantages—that is, less respiratory depression and more rapid recovery—over fentanyl when administered by continuous infusion as an adjuvant to nitrous oxide on an outpatient basis. Of the available IV anesthetic drugs, methohexital sodium may prove to be the most useful for outpatients because its use is associated with a rapid recovery and few, if any, side effects. Additionally, methohexital can be administered by continuous infusion to supplement nitrous oxide. In outpatients receiving fentanyl (75 to 100 μg) or meperidine hydrochloride (50 to 75 mg) for premedication, an induction dose of methohexital, 1.5 mg per kg of body weight, followed by a maintenance infusion of methohexital, 3 to 6 mg per minute, proved to be an excellent adjuvant to nitrous oxide. Further studies are under way to evaluate the use of a methohexital IV infusion for sedation during local or regional procedures. Controlled studies comparing these infusion techniques with the use of volatile anesthetic agents (such as isoflurane) on an outpatient basis are needed.

A wide variety of delivery systems are available for continuous IV administration of anesthetic agents. Although volumetric or syringe pumps are useful for prolonged infusions, simple drip chamber or flow-controller devices are adequate in an outpatient setting. In fact, the drip chamber containing the drug to be infused can be piggy-backed into an existing intravenous line (with or without a flow-controller device). If sterility is maintained, the same infusion system can be used in several different patients. Thus, expensive infusion pumps are unnecessary when continuous administration techniques are used for brief surgical procedures.

In conclusion, continuous intravenous administration of anesthetics (and analgesics) is an acceptable alter-

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native to the volatile anesthetics used in the outpatient setting. For outpatient procedures where volatile agents should probably be avoided (such as a midtrimester abortion), these adjunctive IV infusion techniques are simple to use and associated with a patient's rapid recovery and prompt discharge from the ambulatory surgery facility. With the increasing popularity of IV anesthetics, infusion pumps may soon become standard equipment on anesthesia machines.

Paul F. White, Ph.D., M.D.

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Perfluorochemical Emulsion—'Artificial Blood': What Is It?

Leland Clark dramatically proved the oxygen-carrying ability of perfluorochemicals by completely submerging a mouse in the liquid for 20 minutes and having it survive. These inert liquids have extremely high oxygen solubilities, about 20 times that of water—that is, 45 ml per dl at 760 torr oxygen partial pressure (tension: Po_2) and 37°C; perfluorochemicals are also immiscible in water and are acutely toxic when given intravenously because they form a bolus that acts as a pulmonary embolus. In 1968 it was shown that a fine emulsion of perfluorochemical in saline solution could act as an erythrocyte substitute in rats that have had exchange transfusions. The first human volunteers received the perfluorochemical emulsion, Fluosol-DA (20%), in 1979. Fluosol-DA has 14 grams per dl of perfluorodecalin and 6 grams per dl of perfluorotripropylamine emulsified in a solution of salts and hydroxyethyl starch. Because Fluosol-DA contains only 20 grams per dl of perfluorochemical with an approximate density of 1.8 grams per ml, in a patient having a complete exchange transfusion (fluorocrit about 12%, ml per dl of perfluorochemical in the plasma) at 500 torr arterial oxygen partial pressure (Pao_2), the perfluorochemical would carry about 6 ml per dl of oxygen. This may seem small compared with a normal arterial oxygen content of blood at room air of 20 ml per dl; but because the perfluorochemical transports oxygen by direct solubility as does plasma, nearly all the oxygen in the perfluorochemical is consumed. That is, if an exchange-transfused patient had an arterial-venous oxygen content difference of 4 ml per dl, the mixed venous Po_2 would be more than 150 torr.

Recent clinical studies in the United States and Japan have confirmed that perfluorochemicals do transport the expected volume of oxygen and in spite of the small amounts of perfluorochemical given (fluorocrit 3%), there were significant increases in oxygen content, oxygen consumption and mixed venous hemoglobin saturation. The perfluorochemical is cleared by expiration and has a plasma half-life of about 18 hours. As an erythrocyte substitute, perfluorochemical emulsions will only be beneficial in acute emergencies until blood is available. Because perfluorochemicals carry oxygen by simple solubility like plasma, the amount of oxygen carried is directly related to the Pao_2. It has been shown in a clinical study that a significant increase in oxygen content could only be measured when the perfluorochemical was in the presence of high Pao_2 values (more than 300 torr).

One of the most intriguing properties of perfluorochemical emulsions is the extremely small size of the emulsion droplets, 0.1 micron (1/70 the size of an erythrocyte). With the potential to transport more oxygen through small constricted blood vessels, these fluids may be beneficial in any acute ischemic disease process. Glogar and co-workers showed a significant myocardial protective effect when these fluids were given in an animal model of myocardial infarction. Peerless and colleagues found similar results in an animal model of acute cerebral ischemia.

Perfluorochemical emulsions are intriguing new fluids that should be thought of as "supercharged" plasma and not erythrocyte substitutes. They may support anemic patients but require high oxygen tensions. They will probably play a significant role in the future in emergency treatment of ischemic disease.

Kevin K. Tremper, M.D.

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Transcutaneous Oxygen Partial Pressure: A Continuous Noninvasive Monitor of Tissue Oxygenation

A transcutaneous oxygen sensor measures oxygen partial pressure (Po_2) noninvasively at the skin surface with the same Clark polarographic electrode that is used in conventional blood gas machines. For the sensor to record significant Po_2 values with fast response times on adult skin, the electrode must be heated to 44 °C to 45 °C. Heating the skin causes the stratum corneum to change structure, which is thought to increase its permeability to oxygen. Heating also causes hyperemia of the dermal capillary bed and is said to "arterialize" the capillary blood. Therefore, the transcutaneous Po_2 sensor actually continually measures the Po_2 of heated skin tissue. This technique was first used on neonates in which transcutaneous Po_2 values were reported to nearly equal arterial oxygen tensions (Pao_2). Transcutaneous Po_2 monitoring has now become a standard tool for managing neonates with respiratory distress syndrome.

By the late 1970s it has been noted that transcutaneous Po_2 values were very low in neonates who were hemodynamically compromised. At first these low values were considered faulty and transcutaneous Po_2 monitoring was reported to be "unreliable" during shock states. In 1979 it was shown in animal models that transcutaneous Po_2 follows Pao_2 during hypoxia and follows changes in cardiac output and oxygen delivery during hypovolemic shock and resuscitation. These results have been confirmed in clinical studies of adults. It is now realized that transcutaneous Po_2 values are peripheral tissue oxygen tensions and therefore are more related to changes in oxygen delivery. These values will follow those of Pao_2 when cardiac output is adequate and follow cardiac output and oxygen delivery during low cardiac output, shock and resuscitation. The normal values in adults are about 80% of the Pao_2 when patients are hemodynamically stable (transcutaneous Po_2 [$Ptco_2$] index = $Ptco_2/Pao_2 = 0.79 \pm 0.12$ when cardiac index is more than 2.2 liters per minute per m^2). As cardiac output decreases, the central-to-peripheral-oxygen gradient increases such that the transcutaneous Po_2 is about 50% of Pao_2 when the cardiac index is about 2 liters a minute per m^2 and it is about 10% of Pao_2 when the cardiac index is about 1 liter a minute per m^2 (Table 1).

The in vitro response times of the electrodes are very fast, 95% response in 10 to 20 seconds. The in vivo 95% response of the sensors to changes in inspired oxygen are in the range of two to three minutes, but this lag in response is for the physiologic transport of oxygen to the tissues.

Transcutaneous Po_2 sensors have now been shown to be reliable continuous noninvasive monitors of tissue oxygenation. These values reliably follow the Pao_2 values when the patients are hemodynamically stable and give an assessment of the degree of tissue hypoxia and hypoperfusion during shock and resuscitation. The transcutaneous Po_2 monitor is undoubtedly a significant advance in noninvasive patient monitoring.

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Anesthetic Management of Chymopapain Injections

Each year about 200,000 surgical procedures are performed on patients with "low back pain syndrome." Chemonucleolysis, the injection of chymopapain into a herniated disc, offers an alternative intervention in selected patients. However, there is a 1% incidence of an anaphylactic reaction and a 0.1% chance of a fatal outcome. Chymopapain is now available in a purified form, Chymodiactin, and it produces relief of symptoms in 75% of properly selected patients. Chymodiactin is composed of two proteins that are stablized with sodium cysteinate hydrochloride. Chymopapain hydrolyzes the mucopolysaccharide nucleus pulposus. Chemonucleolysis may be done under general endotracheal or local anesthesia supplemented with sedation or analgesia (or both).

The risk is the development of anaphylactic or anaphylactoid reactions. Anaphylaxis usually requires a previous exposure (chymopapain is used in some nonmedical commercial products) of a patient's lymphocytes to produce IgE-mediated release of histamine and other active substances that dilate arterioles and venules and increase capillary permeability, with massive loss of intravascular fluids and profound hypotension. In addition, bronchospasm, ventricular dysrhythmias, atrioventricular block and coronary arterial spasm may ensue. Anaphylactoid reactions are effected by a direct action on mast cells and basophils producing histamine release and the clinical manifestations may be milder or indistinguishable from those of anaphylaxis.

Patient selection for an allergic diathesis is mandatory: a history of either atopy or allergic drug reactions is a relative contraindication. Women have a fourfold greater chance of a reaction than do men.

Persons with a limited cardiopulmonary reserve should have careful monitoring that includes invasive measures. Monitoring otherwise should include blood pressure measurement, electrocardiogram, precordial or esophageal examination with a stethoscope and temperature recording. The most effective way to alter an immune response to chymopapain is by adequate pretreatment with H_1 (diphenhydramine hydrochloride) and H_2 (cimetidine) receptor antagonists intravenously or by mouth.

A large-bore intravenous line should be used for fluid preloading with up to 2 liters of crystalloid. The following therapeutic drugs should be immediately available: epinephrine, both bolus and drip, diphenhydramine, cimetidine, hydrocortisone, sodium bicarbonate and aminophylline. If an allergic reaction occurs, the surgeon should stop administering the antigenic agent, the patient should be intubated and ventilated with 100% oxygen and appropriate aggressive therapy with intravenous epinephrine must be the mainstay of the initial treatment regimen. Epinephrine stops the allergic reaction and provides cardiovascular support and bronchodilation. Acidosis must be corrected. If the reaction persists beyond these initial maneuvers, then further aggressive pharmacologic therapy with the above-mentioned drugs and fluids must be instituted.

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Intraspinal Administration of Narcotics: A New Approach to Pain

Studies in animals and humans have shown that intraspinally given (epidural or intrathecal) narcotics produce intense and prolonged pain relief. The clinical use of this technique has increased greatly, with the largest study to date reviewing the experience with more than 6,000 epidural or intrathecal administrations of narcotics. Intraspinal administration of narcotics has been used with varying results for obstetrics, postoperative pain and chronic pain. In the last group, experimentation now includes indwelling catheters and drug reservoirs for long-term intraspinal infusion of narcotics in patients with cancer.

Rosen and co-workers showed that 5 and 7.5 mg of *preservative-free* epidurally given morphine was equally effective in relieving the pain of postcesarean delivery patients, whereas 2 mg was totally ineffective. The patients receiving 5 mg of epidural morphine, for example, did not request further analgesic medication until 29 hours (± 2 hours) later. Intraspinal morphine has been used to provide obstetric analgesia. This subject has been reviewed elsewhere and investigation and modification of the technique continues. In general, the intrathecal application of 1 mg of morphine has been successful in relieving the pain of the first stage of labor, whereas 7.5 mg of morphine (or more) is needed to provide relief by the epidural route, and seems less satisfactory than a local anesthetic. As little as 2 to 3 mg of morphine via a thoracic epidural route has been successful for some postoperative patients such as after a thoracotomy.

The intraspinal use of morphine or other opiates in patients who have chronic pain is an expanding area of interest. The finding that 0.5 to 1.0 mg of intrathecally given morphine could provide 10 to 24 hours of pain relief in patients with intractable pain due to malignant disease has led to the investigation of long-term therapy. Of particular interest is an implanted reservoir for continuous treatment of pain with small doses of narcotics. Using this method of administration, patients with terminal illness previously receiving massive doses of narcotics that produced significant sedation were pain free and alert.

The side effects are varied and dose-related. In general, they occur more frequently and with greater intensity after an intrathecal application, compared with epidural administration. Pruritus, the most common side effect, varies greatly in intensity and is of uncertain origin. There is some relief with 25 to 50 mg of diphenhydramine hydrochloride; however, the pruritus is completely relieved by low-dose naloxone hydrochloride in most cases and the analgesia is not reversed. Other side effects include urinary retention, nausea and vomiting, all of which can be treated. The most serious drawback with this technique is *late respiratory depression.* Respiratory depression usually occurs four to eight hours after intraspinal administration, but it can occur ten hours or more after administration. It has been reported with both the intrathecal and epidural administration of even very low doses of narcotics. It is important to stress that analgesia is usually achieved within 30 to 45 minutes, whereas the respiratory depression may occur hours later. Patients who have received epidural or intrathecal morphine must be observed carefully for up to 24 hours. Apnea monitors are being used by some to watch for respiratory depression, while others have had success with careful observation of respiratory rate by the nursing staff. Giving naloxone quickly and easily reverses the respiratory depression and, if small doses are given (0.1 mg intravenously), the analgesia can be maintained. Risk factors for respiratory depression appear to be advanced age, decreased ventilatory capacity and concomitant administration of central nervous system depressants.

In conclusion, it appears that intraspinal administration of narcotics has a role in the treatment of a number of different types of pain. The Food and Drug Administration is considering approving a preservative-free morphine for intraspinal use (A. H. Robins Company, Inc), which may make this method of administration more practical. However, investigation of the drug, total amount to be applied and the route, as well as side effects and potential benefits, continues. The "silver bullet" of pain relief has not yet been found.

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Celiac Plexus Alcohol Block for Upper Abdominal Cancer Pain

The management of intractable pain in patients who have recurrent or nonresectable carcinoma of the upper abdomen is often a major problem for a responsible physician. In this group of patients, celiac plexus alcohol block appears to be the most effective and least hazardous means of palliative therapy.

The celiac plexus provides all of the autonomic innervation of the upper abdominal viscera. Anatomically, it is a retroperitoneal structure located anterior to the aorta at the level of the twelfth thoracic and first lumbar vertebrae. The celiac plexus is comprised of visceral afferent and efferent sympathetic fibers from the fifth thoracic to the second lumbar levels and preganglionic parasympathetic fibers from the vagus nerve.

A diagnostic celiac plexus block should precede therapeutic alcohol neurolysis for three reasons. First, one should ascertain how much pain relief (if any) can be achieved. Second, a diagnostic block allows an anesthesiologist to evaluate appropriate needle depth and position. Third, the physiologic consequences of the block can be appreciated and evaluated when a temporary block is produced. This is accomplished using 0.25% bupivacaine hydrochloride resulting in an 8-to 12-hour block.

The celiac block is done by a posterior approach as described by Kappis in 1919, with the patient awake and in the prone position. For alcohol neurolysis, needle placement should be verified by either x-ray films or computed tomography. The therapeutic block consists of injecting 25 ml of a 50% ethanol solution through each of two 20-gauge needles. Paralysis can result from this block due to faulty needle placement and consequent spread of alcohol into the subarachnoid space, epidural space or onto thoracic and lumbar somatic nerves.

Although it is difficult to define success when treating pain, up to 94% of patients will acknowledge partial to complete pain relief. Most often, the relief is noted within minutes after alcohol injection, though up to 24 hours are needed for maximal effect on occasion. The duration of pain relief postblock is unpredictable, and the block can be repeated as necessary. In many cases, however, patients succumb from the underlying disease before the dissipation of the effects of the neurolytic block. Due to the splanchnicectomy, 85% of patients report dizziness upon sitting for the first time postblock. This resolves in less than a week.

An interesting question is whether celiac plexus neurolysis might result in an acute problem in the abdomen going unnoticed. To date, this risk has not proved worthy of concern.

Continuous intraspinal narcotic administration is currently being offered at selet centers as a "reversible modality" in place of neurolytic therapy for the control of terminal cancer pain. Some of the requirements necessary for its successful implementation include hospital admission (before and after reservior implantation), the devlopment of tolerance requiring adjustment of delivered narcotic concentration and close follow-up for percutaneous refilling of the reservoir. Respiratory depression has not been reported thus far. Neurotoxicity from chronic intraspinal catheters or narcotic infusions (or both) has not been encountered. The use of continuous intraspinal narcotics is in its early stages. Many resources are needed for its successful implementation. At present, continuous intraspinal narcotics for the control of upper abdominal cancer pain should be reserved for patients whose pain is refractory to celiac plexus neurolysis.

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Blood Glucose Homeostasis

The intravenous administration of 10 ml per minute of a 5% glucose solution to a healthy anesthetized patient will result in mild hyperglycemia (200 mg per dl or lower). However, the same infusion rate in a patient with glucose intolerance, such as diabetic or obese persons, will result in a greater degree of hyperglycemia that is of pathophysiologic significance (250 mg per dl or higher). The adverse sequelae of hyperglycemia are distinct from those associated with a ketoacidotic state and have been traditionally overlooked and untreated. These include (1) osmotic diuresis effecting both a hypovolemia and a depletion of potassium, phosphate and sodium. The physiologic disturbances of hypokalemia and hyponatremia are well recognized. Hypophosphatemia causes erythrocyte hemolysis, reduced erythrocyte 2, 3-bisphosphoglycerate content and platelet dysfunction. The intracellular movement of potassium and phosphate occurring with insulin therapy will worsen hypokalemia and hypophosphatemia, and potassium phosphate is the dually effective form of potassium therapy; (2) nonketotic hyperosmolar state, one that can develop even in a person with diabetes previously controlled with diet. Coma and failure to emerge from anesthesia is an ultimate sequela; (3) impaired leukocyte function effecting an immediate increased susceptibility to infection and sepsis; (4) platelet dysfunction that is additive to that induced by hypophosphatemia, and (5) depressed myocardial function and increased ventricular arrhythmias in an ischemic myocardium when a raised free fatty acid level in the blood accompanies the hyperglycemia.

Hyperglycemia in an anesthetized patient is attributable to the metabolic predominance of stress hormones (glucagon, catecholamines and glucocorticoids) and the relative or absolute deficiency of insulin. Appropriate insulin therapy restores glucose tolerance and homeostasis. Only the sympathetic blockade of a regional anesthetic partially ablates this hormonally mediated hyperglycemia.

A rapid, accurate, inexpensive and simple "bedside" technique is now available to anesthesiologists for the measurement and monitoring of blood glucose levels. With this technique reagent strips impregnated with the enzyme glucose oxidase are used with a single drop of blood and, preferably, a reflectance colorimeter. It facilitates deploying any of the several blood glucose management protocols that achieve euglycemia or a minimal hyperglycemia by providing an anesthetized patient with a more constant physiologic level of circulating insulin. Serial glucose measurements verify both absolute blood glucose concentrations and trends.

Hypoglycemia is the major complication of physiologic insulin therapy management plans. For an anesthetized patient hypoglycemia is a much more dangerous condition than is hyperglycemia because it leads to severe injury of the central nervous system. As the brain is absolutely dependent on glucose for energy, hypoglycemia is the biochemical equivalent of hypoxia. Anesthesia can mask, modify or abolish any or all of the clinical manifestations of hypoglycemia, and therefore, only the frequent monitoring of blood glucose levels can protect against the development of hypoglycemia. A blood glucose level of 65 mg per dl is considered a potentially significant hypoglycemia in an anesthetized nondiabetic person, but a value of less than 100 mg per dl should evoke appropriate glucose therapy in an anesthetized diabetic person receiving insulin.

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Interactions of Calcium Channel Blockers With Anesthetic Agents

Verapamil, nifedipine and diltiazem hydrochloride were all released for clinical use in the United States with little understanding of their interactions with anesthetic agents. These calcium channel blockers, which inhibit the voltage-dependent influx of mainly calcium ions through the slowly activated ionic channels of excitable cell membranes, have the potential to interfere with intracardiac impulse conduction and to inhibit myocardial and vascular smooth muscle contractility. They have already been widely applied in the treatment of obstructive and vasospastic angina pectoris, while verapamil is used for the treatment of paroxysmal supraventricular tachycardia and to slow the ventricular rate in atrial fibrillation and flutter. Calcium channel blockers have possible applications in the treatment of hypertrophic obstructive cardiomyopathy, hypertension and peripheral vasospastic disorders, and may play a role in myocardial preservation techniques. Many patients taking these drugs on a long-term basis can be expected to undergo anesthesia and a surgical procedure. Opportunities regularly arise for the intraoperative and perioperative use of these drugs.

Generally, additive hemodynamic depressive effects are found when calcium channel blockers are combined with inhalation anesthetic agents such halothane, isoflurane or enflurane, effects that are related both to the anesthetic concentration and to the dose of the calcium channel blocker. The inhalation agents themselves are known to adversely affect calcium homeostasis, and, in addition, inhalation anesthetics may blunt some of the autonomically mediated compensatory reflexes that serve to mitigate the direct cardiovascular depressant effects intrinsic to the calcium channel blockers. Additional care must be taken if compensatory reflexes are further diminished by β-blockade or other autonomic nervous system disorders, or if patients have preexisting left ventricular dysfunction. In autonomically intact anesthetized persons, however, nifedipine usually exerts a predominantly vasodilating effect, while verapamil exhibits a dose-dependent depression of myocardial contractility as well. Interference with intracardiac conduction by verapamil, as evidenced by prolongation of the PR interval on an electrocardiogram, is also found in anesthetized patients.

Modest decreases in blood pressure and peripheral vascular resistance have been noted in persons under narcotic-based anesthesia after receiving either verapamil or nifedipine. The effects of high-dose narcotic anesthesia in persons on long-term nifedipine therapy is the subject of current investigations. Verapamil and nifedipine have been shown to potentiate the effects of both depolarizing and nondepolarizing neuromuscular blocking drugs. It remains to be determined whether any clinically significant prolongation of neuromuscular blockade can be seen in patients receiving calcium channel blockers.

Doses of either anesthetic agents or calcium channel blockers should be titrated to clinical effect in the presence of the other. If undesired cardiovascular effects occur, contributing inhalation agents can be reduced or eliminated, calcium can be infused or an infusion of a β-agonist initiated. Prolonged conduction block can be treated with a temporary pacemaker. The benefits of calcium channel blockade during anesthesia can usually be achieved, and complications avoided, by a thorough understanding of their pharmacology and anesthetic interactions.

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National Institutes of Health Consensus Development Program

MICHAEL J. BERNSTEIN

Can analgesics alone, or in combination, cause kidney disease and chronic kidney failure? Should all pregnant women have diagnostic ultrasound imaging examinations? Is the quality of life better as a result of coronary bypass surgery in the majority of patients?

These are some of the key questions addressed at the National Institutes of Health Consensus Development Conferences. The Consensus Development Program, since its creation in fall 1977, has been a major technology assessment activity at the NIH, bringing together experts, medical generalists, research scientists, practitioners and members of the public to evaluate drugs, devices and procedures for safety and effectiveness.

The program was launched to improve the lines of communication from the health research community to the practicing physician and the public. It is designed to complement the usual means of reporting research results through publication in scientific journals and other medical periodicals and through the lay media.

NIH started the technology assessment activity because there was no formal process within the research community to assure that medical discoveries were identified and evaluated to determine if they were ready to be used by physicians and other health care professionals. Since NIH is the nation's principal health research agency, it was felt that it should assume the responsibility of more fully reporting biomedical research findings to the practicing community and the public.

In the 1970s there was considerable public criticism voiced concerning the use of certain surgical and medical procedures, drugs and devices. Many claimed that some new technologies had reached the health care delivery system without being tested adequately. On the other hand, some maintained that some well-validated technologies had been too slow in making their way from the research workbench to the hospital bedside and the physician's office. To aid in the transfer process, the current program was created.

A main objective of consensus conferences is to provide the physician and the public with current, responsible information on the advantages and disadvantages of specific medical and surgical and dental procedures, drugs, and devices. The value of this information is that it calls attention to safe and effective emerging or underused technologies and makes a wider audience aware of their availability. At other times, consensus reports may point out some potential problems which could result from the use of an existing technology. And in some instances, consensus conferences recommend against using a given drug, device or procedure.

For example, a recent consensus conference recommended against the use of combination antipyretic analgesics citing scientific data indicating that such agents can cause kidney disease if used in large doses over long periods of time. Another conference concluded that routine diagnostic ultrasound screening during pregnancy was not proven to be useful. A third consensus conference said that while coronary bypass surgery has been shown to relieve pain markedly and improve functioning of the heart, existing data did not show a high percentage of bypass patients were able to go back to work full time.

On the more positive side, the use of dental sealants to prevent tooth decay was lauded by one consensus conference and another group urged wider use of thrombolytic agents to treat thrombosis. And last year a consensus conference supported liver transplantation for certain categories of patients.

To date, NIH has held 44 Consensus Development Conferences. Although the subjects and findings have been varied, once a topic has been chosen for assessment, each meeting does have one common element.

MICHAEL J. BERNSTEIN, Director of Communications for the Office of Medical Applications of Research, National Institutes of Health.

There is certain to be more than a year of intensive, detailed planning before the first speaker walks up to the podium in Masur Auditorium in the NIH Warren Grant Magnuson Clinical Center and begins a scientific presentation.

Topics selected for consensus conferences may be suggested by the NIH Bureaus, Institutes, or Divisions, other federal, state or local health agencies, health care organizations, the public, or the Office of Medical Applications of Research (OMAR), the focal point for technology at NIH. OMAR, part of the Office of the Director, NIH, coordinates the Consensus Development Program.

To be chosen as a consensus topic, the technology must meet certain criteria. Most importantly, there must be an adequately-defined and available data base of scientific information to answer a set of questions regarding the safety and efficacy of the drug, device or procedure under review. In addition, the subject must be medically important; there should be scientific controversy surrounding the technology or a gap between current knowledge and practice that a consensus conference might narrow; and the timing of the conference should be such that it is likely to have a meaningful impact.

It also is important that the topic will affect a significant number of people; it may have federal reimbursement implications; it will have preventive impact, and it will be of public interest.

Once a topic is chosen, the OMAR staff and scientific experts from the sponsoring organization (most often an NIH Bureau, Institute or Division, sometimes collaborating with another federal health agency) begin the planning process.

The sponsor designates a coordinator for the conference who serves as the primary meeting organizer and usually chairs a planning committee. OMAR also names a coordinator for the conference and the two persons and other staff select members of the conference planning committee. The committee usually is composed of representatives of OMAR, the sponsoring Institute, Bureau or Division and three experts outside the Federal Government.

The planning committee has four major functions:

- To draft consensus questions
- To draft the conference program
- To recommend conference speakers
- To recommend Consensus Panel members

In choosing a chairperson, the committee seeks a knowledgeable and prestigious figure in the field of medical science under consideration. But that person should not be identified with strong positions of advocacy on one side or another of the consensus topic.

The agenda for a consensus conference is structured around key questions posed to the panel that serve to determine the scope and substance of the meeting. These questions, drafted months before the conference, normally number from four to six, with one dealing with panelists' opinions on directions for future research.

The first day-and-a-half of the program is a plenary session in which experts present evidence on the technology being evaluated. There are several open discussion periods during which the audience has ample time to raise questions or clarify points. These conferences are open to the public at no charge.

Throughout the plenary session, panel members take part in the audience discussion and continue to weigh the scientific evidence in preparation to drafting a consensus statement which will answer the meeting questions. The panel begins to write its report on the first night of the conference and then works on the draft at the close of the plenary session—usually at noon on the second day—and does not adjourn its executive session until it has finished. This drafting frequently takes 12-15 hours. In addition to hearing the scientific presentations and audience discussion, the panel receives written papers and, in some instances, position papers on the technology being reviewed. The objective is to provide members with all the information they need to answer the questions clearly, concisely, and in a straightforward manner.

Besides the developing of a good set of questions and the choosing of an efficient chairperson and knowledgeable speakers, selecting a balanced, conscientious panel is critical to the success of any Consensus Development Conference. It is important that the panel be broadly based because a range of expertise affects the panel's ability to deal with the varied scientific material presented in the plenary session. In addition, a diversified panel enhances the credibility of the consensus statement in that the conclusions are not only those of proponents or practitioners of a particular technology.

Panels generally have from 10-16 members. They include research investigators in the field under review; health professionals who are users of the technology, including practicing internists, surgeons, pediatricians, family practitioners, nurses and other members of the health care team; methodologists or evaluators such as epidemiologists and biostatisticians; and public representatives such as ethicists, lawyers, economists, theologians, public interest group representatives and patients. Because the report prepared by the panel is not a federal document, government employees generally are not named to panels and a panel chairperson always is chosen from the private community.

On the final morning of the conference, the panel chairperson reads the draft consensus statement to the audience and a period of open discussion follows during which questions, suggested additions and corrections are solicited. The final draft, which is released by the panel a few weeks after the meeting, invariably contains a number of modifications recommended by members of the audience. After the discussion period, a press conference is held, launching the dissemination phase for the meeting. As many as 60 medical and lay media members have attended a given consensus press conference. When the panel produces its final version of the report, OMAR has the statement printed and distributed to more than 20,000 health care professionals, research scientists, members of the public and health care organizations. For example, continuing medical education directors at the more than 7,700 American Hospital Association institutions receive the final consensus reports after every Consensus Development Conference.

In addition, major general medical journals—such as the *Journal of the American Medical Association*—are asked to publish the consensus statement and key specialty periodicals and lay mass media magazines receive copies. Notices of the availability of the consensus report also are sent to hundreds of journals, magazines and newsletters. Besides the publication of these reports in *JAMA*, the *New England Journal of Medicine*, the *Annals of Internal Medicine*, *The Lancet*, the *British Medical Journal* and state medical journals, the lay media has covered the conferences widely. As many as 250 newspapers have printed stories concerning a particular consensus conference. And local and national television news shows—including the Today Show, Good Morning America, The ABC, NBC, CBS network news and the MacNeil/Lehrer Report—have devoted air time to reporting on these meetings.

In the first six-and-a-half years of the program, Consensus Development Conferences have focused on a wide range of medical technologies. There are still many more that need to be evaluated and the consensus calendar is already filled through the summer of 1985. Dates have been set for the following topics:

Fresh Frozen Plasma: Indications and Risks, September 24-26; Limb-Sparing Treatment of Adult Soft Tissue and Osteogenic Sarcomas, December 3-5; Lowering Blood Cholesterol to Prevent Heart Disease, December 10-12; Traveler's Diarrhea: Prophylaxis and Treatment, January 28-30; Health Implications of Obesity, February 11-13; and Anesthesia in the Dentist's Office, April 22-24.

As the Consensus Development Program matures and as the years pass from the time conferences are held, a new need arises: to revisit some of the topics for updating findings. In the next few years OMAR and the other NIH sponsors of consensus conferences plan to review some of the topics assessed several years ago. A second consensus conference may be planned or some other form of reevaluation may be undertaken. Whatever method is used, the Consensus Development Program will continue to be designed to provide the physician and the public with the best, most current information on medical technologies in an effort to improve the quality of health care for all.

Single copies of the 1984-85 Consensus Development Calendar may be obtained from the Office of Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205.

MEDICAL LICENSURE BOARDS will be notified by the AMA when a physician loses his license for incompetence, AMA Trustee John J. Ring, M.D., told the Senate's Special Committee on Aging. The AMA is concerned that health care practitioners who have been found unfit to practice in one jurisdiction are able to relocate and practice in another jurisdiction where they hold a license. Using the AMA Physician Masterfile, the Association will send information on a disciplinary action in one state to all other states where the physician has held a license. The Physician Masterfile appears to be the only multistate data base on physician licensure. Dr. Ring, a physician in general practice in Mundelein, Ill., said the AMA traditionally has cooperated with state licensing boards, but few routinely take advantage of the Association's resources. The AMA has a policy of terminating a physician's membership if his license is revoked for cause, Dr. Ring said. If the physician joined through the state society, the AMA encourages the society to take action.

—*AMA Newsletter*, July 3, 1984

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Analgesic–Associated Kidney Disease

NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

Introduction and Conclusions

Introduction

Ingestion of large amounts of some pain-relieving drugs over long periods of time has been shown to be associated with the development of one type of kidney disease that can lead to kidney failure. Since this problem was first reported in the 1950s, analgesic-associated kidney disease has become recognized as a significant, costly, and potentially preventable and treatable health problem. While research has shown an association of analgesic ingestion with kidney disease, there continues to be debate about the specific drugs that cause it, the mechanisms by which renal damage occurs, and the extent to which this illness may contribute to the overall burden of chronic renal disease in our society. The distributor and prevalence of analgesic-associated kidney disease appear to vary widely in different countries of the world and within the countries where it has been shown to occur.

In an effort to resolve some of the questions about this type of kidney disease, the National Institutes of Health convened a Consensus Development Conference on Analgesic-Associated Kidney Disease on February 27-29, 1984. After a day and a half of scientific presentations by experts of the available data about the problem, a Consensus Panel including representatives of the fields of nephrology, pathology, internal medicine, family medicine, pharmacology, biostatistics, and epidemiology, and of the general public considered the scientific evidence and agreed on answers to the following questions:

1. Can analgesics, alone or in combination, cause kidney disease and chronic kidney failure? What evidence supports these conclusions?
2. What are the scope and characteristics of the problem of kidney disease caused by excessive use of analgesics in the United States and in other countries?
3. What causes analgesic-associated kidney-disease?
4. What factors increase the risk of occurrence of analgesic-associated kidney disease?
5. Can analgesic-associated kidney disease be prevented?
6. What treatment strategies are appropriate?
7. What are the directions for future research?

Panel's Conclusions

Considerable evidence indicates that combinations of antipyretic analgesics, taken in large doses over a long period of time, cause a specific form of kidney disease and chronic renal failure. Persons so exposed may also be more susceptible to the subsequent development of uroepithelial tumors. In contrast, there is little evidence that preparations containing a single analgesic agent have been similarly abused and are similarly harmful.

The occurrence of analgesic-associated nephropathy shows striking geographical differences. Such differences may be related, at least in part, to regional variations in the habitual consumption of antipyretic-analgesic mixtures. The pathogenesis of the condition is uncertain but may involve a direct cytotoxic action of the

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From the Office of Medical Application of Research, National Institutes of Health, Bethesda, Md.

Reprint requests to the Office of Medical Applications of Research, Room 216, National Institutes of Health, Bethesda, MD 20205 (Michael J. Bernstein).

analgesics on the renal papilla, perhaps enhanced by ischemia.

The sustained use of mixtures of antipyretic analgesics in large doses is not advisable. Serious consideration should be given to limiting over-the-counter products to those containing a single antipyretic-analgesic agent.

1. Can analgesics, alone or in combination, cause kidney disease and chronic renal failure? What evidence supports these conclusions?

The weight of evidence supports the view that combinations of antipyretic analgesics taken in large doses over long periods of time can cause kidney disease and chronic renal failure.

No evidence has been presented, however, to indicate that single anti-pyretic-analgesic drugs cause chronic renal disease when taken in the smaller doses usually prescribed by physicians or taken for valid medical reasons in doses recommended by the manufacturer.

Three types of evidence support these conclusions.

1. Clinical. A characteristic clinical and pathological picture of a chronic tubulo-interstitial disease of the kidneys has emerged from many case reports. It is seen in patients who have consumed large quantities of antipyretic-analgesic mixtures, often in powder form. The disease is slowly progressive and commonly asymptomatic until severe renal failure occurs, although renal damage can be detected earlier by laboratory tests of the kidney's excretory or concentrating abilities. Papillary necrosis and interstitial scarring are characteristic; the disorder may be manifest clinically by urinary passage of necrotic tissue or by urography and signaled by sterile pyuria and low fixed urinary specific gravity.

The condition is seen mainly in women who take large doses of analgesic mixtures daily over long periods of time. Many of them may also exhibit gastrointestinal disorders, anemia, and emotional disturbances.

When persons with analgesic nephropathy stop ingesting analgesic mixtures, progression of the renal disease may be retarded or even reversed. In contrast, if they continue to consume the analgesics, the disease usually progresses.

2. Epidemiological. Although the epidemiological evidence is limited, certain studies, especially in areas of high consumption outside the United States, support an association between the heavy use of analgesic mixtures and chronic renal disease, particularly papillary necrosis. For example, in one geographic area, the relative risk for developing papillary necrosis was 17 times higher in heavy users than in non-users. In another, prolonged use of phenacetin-containing analgesics by a group of working women studied over a 10-year period was associated with a significant increase in impaired renal function; an increased mortality from cardiovascular and renal disorders was also reported.

Analgesic nephropathy, including papillary necrosis, is most common in regions where the consumption and/or sale of analgesic mixtures is high. Furthermore, where the sale of such compounds has been effectively restricted, the prevalence of the disease appears to have diminished.

Certain evidence also suggests that very heavy and sustained use of some analgesic mixtures may predispose to cancer of the urinary tract, particularly transitional cell carcinoma of the renal pelvis.

3. Experimental. Large doses of analgesics, including aspirin, phenacetin, acetaminophen, and combinations of these, cause renal papillary necrosis in animals. The period of drug exposure in animal studies has been shorter than that in humans, while the dose necessary to produce injury has often been very high. For these and other reasons, the applicability of animal studies to human disease may be questioned; nevertheless, the demonstration in animals of a type of nephrotoxicity similar to that reported in humans lends weight to a casual association between analgesic abuse and kidney disease. The results of laboratory studies have suggested biochemical mechanisms by which phenacetin or its metabolites, as well as salicylates, may produce tissue damage in the kidney.

2. What are the scope and characteristics of the problem of kidney disease caused by excessive use of analgesics in the United States and in other countries?

Determining the magnitude and scope of the problem of analgesic-associated nephropathy is difficult. It is relatively easy to identify patients with analgesic nephropathy who have advanced or end-stage renal disease, but earlier or milder cases are difficult to identify. However, the latter must be taken into account to assess fully the potential public health problem.

The magnitude of the problem in its various degrees of severity can be viewed in at least three ways: the frequency of occurrence in the population at large, the frequency of occurrence in persons taking antipyretic analgesics, and the burden that treating the condition imposes on medical and financial resources.

1. Frequency in the General Population. In the United States, end-stage renal disease due to analgesic nephropathy is rare, occurring roughly on the order of one new case per million population per year. However, in some areas, such as parts of the Southeast, where the use of powders containing combinations of analgesics is more common, the incidence is higher, perhaps on the order of 10 per million per year. The incidence is also higher in areas of Belgium, Australia, and Scotland; in Switzerland, the crude incidence has been estimated to be as high as 15 per million per year.

Data on the incidence or prevalence of less severe analgesic nephropathy in the general population are limited, but its frequency is probably several times that of end-stage analgesic nephropathy.

2. Frequency in Analgesic Users. The proportion of analgesic users who develop analgesic nephropathy is not known. Evidence of at least moderately impaired kidney function was found to occur in a substantial proportion of a group of working women in Switzerland who took phenacetin-containing analgesics regularly.

There is no evidence that persons taking any antipyretic analgesics occasionally for headaches or other pains develop analgesic nephropathy. Similarly, advanced analgesic nephropathy is rare even among patients for whom regular or frequent use of analgesics is prescribed by physicians. The lack of data about the extent of use of these drugs in the general population, particularly heavy use, makes it very difficult to correlate the occurrence of analgesic nephropathy with the amount of analgesics taken by individuals.

3. Financial and Medical Care Burden. In most of the United States, analgesic nephropathy accounts for about 2 percent of end-stage renal disease. In northwestern North Carolina, this figure may be as high as 10 percent. If we assume the 2-percent figure, the minimal cost of caring for such patients nationally would be at least $40 million per year, given an estimated annual cost for end-stage renal disease of $2 billion. Thus, even though severe renal failure due to analgesic nephropathy is infrequent in the United States, its financial impact on society is significant.

There are no data to indicate the undoubtedly substantial costs of care for less severe analgesic nephropathy.

3. What causes analgesic-associated kidney disease?

Four clinical and experimental features are relevant to the pathogenesis of analgesic nephropathy. (1) The disease is most commonly associated with the ingestion of analgesic mixtures in large doses over a prolonged time. (2) The initial lesion occurs in the papilla; changes in the cortex are secondary to papillary damage. (3) Papillary necrosis may be accentuated experimentally and in certain patients by dehydration and low urine volumes. (4) The major phenacetin metabolite, acetaminophen, as well as salicylates, is concentrated on the papilla, particularly during low urine output. These features suggest that the disease results from the effects of a toxic agent or agents in the renal papilla, but the precise pathogenetic mechanisms are still unclear.

Present evidence suggests that acetaminophen causes tissue injury as a result of its conversion to toxic metabolites. By lowering the concentration of glutathione, a substance that protects against such tissue injury, aspirin and other salicylates enhance toxicity. Salicylates and acetaminophen also inhibit prostaglandin synthesis and thus may, by reducing medullary blood flow, potentiate papillary damage. These data offer attractive though yet unproven explanations for the synergistic effects of phenacetin and aspirin in causing papillary necrosis. They also suggest avenues for research into interactions of other analgesic and anti-inflammatory drugs that may lead to renal disease.

4. What factors increase the risk of its occurrence?

Clinical studies suggest that the risk of developing analgesic nephropathy depends largely on the magnitude and duration of consumption of analgesic mixtures. This in turn is often influenced by cultural acceptance, promotion and availability of the drugs, occupational stress, and regional patterns of overuse of analgesics. Consumption of over-the-counter analgesic mixtures may be enhanced by the inclusion of stimulant drugs such as caffeine and the packaging of the compounds as powder. Additional risk factors, such as hot climate, laxative abuse, and genetic predisposition, have been suggested but not established.

5. Can it be prevented?

Current evidence suggests that the key to the prevention of analgesic nephropathy is to halt the inappropriate use of analgesics. It should therefore be possible to adopt measures to reduce its incidence substantially, as has already been undertaken in Canada.

Inasmuch as no therapeutic indication has been established for combining antipyretic-analgesic agents, serious consideration should now be given to the withdrawal of such mixed analgesic drugs from over-the-counter use in the United States. Such a measure appears to have reduced the occurrence of analgesic nephropathy in several countries. In Australia, however, when phenacetin in analgesic mixtures was replaced by either salicylamide or acetaminophen, the incidence of end-stage renal disease due to analgesic nephropathy did not fall.

Preparations containing single anti-pyretic analgesics such as aspirin or acetaminophen should remain available as over-the-counter medications, since there is no evidence that their occasional use is related to analgesic nephropathy. The risk from prolonged use of single-ingredient analgesics appears to be small. Patients who require prolonged high intake of analgesics, however, including non-steroidal anti-inflammatory drugs, should be observed for the possible appearance of renal dysfunction at an early and potentially reversible stage. A high fluid intake, especially in warm climates, may be helpful in avoiding concentration of salicylates or acetaminophen in the renal papilla.

6. What treatment strategies are appropriate?

Patients with an established diagnosis of analgesic nephropathy should avoid taking antipyretic analgesics, especially of the mixed variety. If renal insufficiency is not advanced, renal function is likely to stabilize or even improve when analgesics are stopped. Even when renal insufficiency is well advanced, cessation of analgesic intake often slows the rate of loss of renal function.

The main strategies of management must include:

1. Avoidance of antipyretic-analgesic agents, as well as nonsteroidal anti-inflammatory drugs.

2. Prompt treatment of proven urinary tract infections.
3. Awareness that a necrotic papilla may slough and obstruct the urinary tract, sometimes requiring prompt intervention to prevent further loss of renal function.
4. Careful supervision of hypertension.
5. Recognition that tumors of the urinary tract may occur more frequently in patients with analgesic nephropathy. Unexplained episodes of hematuria, including a marked increase in microscopic hematuria, should therefore be evaluated carefully.
6. Consideration of the non-renal manifestations of the analgesic abuse syndrome.

7. What are the directions for future research?

Epidemiological research is needed in several areas. More data are needed on the prevalence and extent of analgesic use, as well as the characteristics that predispose persons to heavy use and abuse, in each region of the United States. There is a need to evaluate the impact of measures designed to reduce analgesic abuse on the incidence of analgesic nephropathy. Moreover, it is important to establish the incidence of analgesic nephropathy in users of single-ingredient analgesics, as well as of nonsteroidal anti-inflammatory agents. Further basic epidemiological research is needed to elucidate the relationship between analgesic use and mild forms of the disease.

It seems possible that certain people are more susceptible than others to kidney injury from analgesics. Research is needed on the factors that may predispose patients to such injury. These include genetic constitution, variations in drug disposition, physiological factors such as hormonal status or state of hydration, sex, age, and environmental circumstances.

While some of the chemical reactions leading to the formation of cytotoxic metabolites have been characterized, further basic research is needed to study the nature of the toxic metabolites, the ultimate mechanisms of acute and chronic cell injury in various components of the papilla, the role of ischemic versus toxic factors, and the interactions among various drugs in causing papillary damage. More information is required on the relationship between analgesic nephropathy and uroepithelial cancer.

The conference was sponsored by the following: National Institutes of Arthritis, Diabetes, and Digestive and Kidney Diseases, Lester B. Salans, M.D., Director, and Office of Medical Applications of Research, J. Richard Crout, M.D., Director.

Members of the Consensus Development Panel were: Roscoe R. Robinson, M.D., (Chairman), Vice Chancellor for Medical Affairs and Professor of Medicine, Vanderbilt University Medical Center, Nashville, Tennessee; Ramzi S. Cotran, M.D., Mallory Professor of Pathology, Harvard Medical School, Pathologist-in-Chief, Brigham and Women's Hospital, Boston, Massachusetts; John S. Derryberry, M.D., Past President, American Academy of Family Physicians, Shelbyville, Tennessee; Jose A. Diaz-Buxo, M.D., Medical Director, Metrolian Kidney Center, Charlotte, North Carolina; Michael Dunn, M.D., Hanna Payne Professor of Medicine, Case Western Reserve University School of Medicine, Director, Division of Nephrology, University Hospital, Cleveland, Ohio; Franklin H. Epstein, M.D., Professor of Medicine, Harvard Medical School, Beth Israel Hospital, Boston, Massachusetts; Gary D. Friedman, M.D., Assistant Director for Epidemiology and Biostatistics, Department of Medical Methods Research, Kaiser-Permanente Medical Care Program, Oakland, California; James Grizzle, Ph.D., Professor, Department of Biostatistics, University of North Carolina School of Public Health, Chapel Hill, North Carolina; Robert G. Luke, M.D., Director, Division of Nephrology and Nephrology Research and Training Center, University of Alabama at Birmingham, Birmingham, Alabama; John M. Newmann, Ph.D., President, National Association of Patients on Hemodialysis and Transplantation, Health Management Consultant, Brookline, Massachusetts; James W. Russell, M.D., Internist, Northeastern Vermont Regional Hospital, St. Johnsbury, Vermont; Irwin M. Weiner, M.D., Professor and Chairman, Department of Pharmacology, State University of New York Upstate Medical Center, Syracuse, New York.

Members of the Planning Committee were: Nancy Boucot Cummings, M.D., (Chairman), Associate Director, Kidney, Urologic, and Hematologic Diseases, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, Maryland; James E. Balow, M.D., Chief, Clinical Nephrology Service, Senior Investigator, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, Maryland; William M. Bennett, M.D., Professor of Medicine and Pharmacology, Division of Nephrology, Oregon Health Sciences University Portland, Oregon; James Bilstad, M.D., Deputy Director, (Medical Affairs), Office of Biologics, Research and Review, Food and Drug Administration, Rockville, Maryland; Vardaman M. Buckalew, Jr., M.D., Professor of Medicine and Physiology, Bowman Gray School of Medicine, Winston-Salem, North Carolina; Martin Goldberg, M.D., Taylor Professor of Medicine, Director, Department of Internal Medicine, University of Cincinnati Medical Center, Cincinnati, Ohio; Robert H. Heptinstall, M.D., Baxley Professor of Pathology, Johns Hopkins University School of Medicine, Johns Hopkins Hospital, Baltimore, Maryland; Judith K. Jones, M.D., Ph.D., Special Assistant to the Director, Office of Epidemiology and Biostatistics, National Center for Drugs and Biologics, Food and Drug Administration, Rockville, Maryland; Fitzhugh Mullan, M.D., Chief Medical Officer, Office of Medical Applications of Research; Office of the Director, National Institutes of Health, Bethesda, Maryland; Roscoe R. Robinson, M.D., Vice Chancellor for Medical Affairs and Professor of Medicine, Vanderbilt University Medical Center, Nashville, Tennessee.

Physician Reimbursement Under Medicare: Reimbursement Options

AMERICAN MEDICAL ASSOCIATION

Mr. Chairman and Members of the Committee:

I am James S. Todd, M.D. I am a physician in the practice of general surgery in Ridgewood, New Jersey, and I am member of the American Medical Association's Board of Trustees. Accompanying me is Ross N. Rubin, Director of the AMA's Department of Federal Legislation. The American Medical Association appreciates this opportunity to present testimony today on the subject of physician reimbursement under Medicare and reimbursement options for physician services.

Before examining the issue of physician reimbursement under Medicare, we believe it is essential to examine Medicare's purposes and accomplishments. The creation of the Medicare program in 1965 was a commitment to the elderly by the Congress that this nation would assure them access to, and meet the major part of the cost of, high quality health care services. That promise, to a large extent, has been met. The eighteen years since the enactment of Medicare have seen tremendous improvement in not only access to and the availability of high quality health care, but in the health care status of the covered population. One of the principal reasons why the Medicare program has been able to accomplish these important twin goals of ready access to high quality care and improved overall health status has been the ability of the Medicare beneficiary to receive care in the same mainstream fashion as other individuals not covered by federal programs.

Physicians have chosen to participate freely in the Medicare program through their treatment of Medicare beneficiaries. Even though the level of physician reimbursement under the Medicare program has not kept pace with the rest of the economy and other reimbursement mechanisms, the percentage of physicians treating Medicare patients has remained relatively constant, with 87.1% of physicians treating Medicare patients in 1982.

The American Medical Association realizes that the Medicare program experiences substantial outlays for physician services. This reflects the fact that the current population of the program is estimated to include 26.6 million elderly and 2.7 million disabled, and it is further estimated that 18.4 million aged and 1.8 million disabled beneficiaries will receive covered services this year. This segment of the population reflects a group with significantly greater needs for medical services that does the population as a whole. Expenditures for the Part B program for physician services in 1984 have been estimated at $15.3 billion.

Background

Health Care Costs

Health care costs in this country, including the dollars for physician reimbursement, have been steadily increasing. In 1965, total health care expenditures were approximately $39 billion and represented 5.9% of the gross national product (GNP). In 1982, these figures had increased to approximately $321 billion, and the percentage of GNP for health expenditures was at approximately 10.5%. The Administration's projections indicate that total health care expenditures will exceed $750 billion by 1990, and this will account for approximately 12% of the GNP.

There has been a great deal of concern expressed about the growth of health care expenditures in this country. It is important to point out, however, that the United States is in no way unique in the amount of resources allocated to health care. Available data show that the average annual rate of increase for health care expenditures experienced in the United States was less than that seen in many western nations. The average annual rate of increase for total health care expenditures in the United States from 1969 to 1976 was 12.5%. However, this figure was higher in Australia (20.5%), Finland (18.9%), the Netherlands (18.4%), the United Kingdom (18.2%), West Germany (17.7%), France (16.5%), Sweden (14.6%), and Canada (14.3%). In ad-

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Statement of the American Medical Association to the Special Committee on Aging, United States Senate. Presented by James S. Todd, M.D.

dition, the analysis of national health expenditures in these nine countries indicates that the percentage share of GNP for health care expenditures in the United States is not out of line with that of the other countries. While the share of GNP in the United States was 8.7% in 1976, Netherlands, West Germany, France, and Sweden all had percentage expenditures greater than 8.2%; Australia, Finland, and Canada all had expenditures greater than 7%; and only the United Kingdom had an expenditure that was less than 6%. We point out these national health care expenditure figures for other countries to show that the United States is not alone in recognizing the importance of health care for its citizens.

Health care costs are not immune to outside market forces. A significant percentage of health care cost increases is attributable directly to the severe inflation that has beset our economy. As a matter of fact, the element contributing the most to the growth in expenditures for health care from the period 1971 to 1981 has been the general inflation affecting the economy. According to an article published in the March 1983 issue of *Health Care Financing Review,* general inflation "accounted for approximately 57% of the increase in total systems costs (personal health care costs) for the period 1971 to 1981." In addition, approximately 8% of the growth in expenditures is directly attributable to the aggregate population growth over that period of time.

A review of health care costs in this country cannot be divorced from the fact that the mix of services available involves more sophisticated technology that is being continually updated. Technological advances have served to improve the overall quality of health care that is available, and they have also served to increase the overall cost of health care services.

An additional reason for increased health care expenditures, including physician reimbursement, is the aging of our population. Health care expenditures and the federal responsibility for health care coverage through Medicare will increase over time as the population and elderly population in particular increases. Between 1983 and 2025, the total population is projected to grow by almost 30 percent, with the elderly population doubling to a total of 58 million or 19.4 percent of the total population. Among the elderly, the group over age 75 will also experience substantial growth: 40 percent of the elderly are now older than age 75, and this figure will increase to 45 percent in 2025; and the over age 85 group will triple from the current 2.5 million people to 7.6 million people in 2025. This substantial increase in the elderly population is particularly important as the elderly have historically utilized a greater proportion of health care resources.

In 1978, the average per capita expenditure for health care by Medicare-eligible individuals was $2,026. The significance of this figure is illustrated by the fact that average per capita spending for individuals between the ages of 19 and 64 totalled $764, and for individuals under age 19 the figure was $286. The statistics also indicate that individuals over the age of 65 are more likely to be hospitalized than those under that age; they use more hospital days per hospitalization; and they visit their physician and other health care practitioners more frequently. The importance of these figures is clear: as the population ages, demands for health care services correspondingly increase and the total cost for providing those services increase.

The AMA does recognize that some health care services should be examined for their cost-effectiveness. We have been taking positive actions to review the delivery of health care services and to eliminate those health care costs that are inappropriate and that are not benefiting the public.

Physician Reimbursement and Beneficiary Liability

An important factor that has enabled physicians to treat their Medicare patients in the same manner as other patients is that there is no need for a physician to differentiate between patients who are Medicare beneficiaries and other patients when it is time to submit bills for services. According to a 1979 General Accounting Office (GAO) report, physicians usually charge Medicare patients the same as other patients. However, the report goes on to indicate that physicians are generally allowed less for similar procedures under the Medicare program.

The American Medical Association fully recognizes that a central issue before the Committee today is the amount of personal liability individual Medicare recipients experience when faced with a physicians' bill for services. First of all, a substantial portion of individual liability is directly related to the mandated deductible and coinsurance requirement—an amount often paid by private supplemental (Medigap) insurance. Also, only a portion of liability is directly related to physician charges that are above the Medicare allowed amount. Furthermore, beneficiary liability beyond coinsurance and deductible responsibility is generally not substantial. The following facts must be kept in mind:

- physician charges to Medicare beneficiaries are in harmony with charges to non-Medicare beneficiaries;
- The application of the economic index has served to arbitrarily increase beneficiary liability;
- Approximately two-thirds of all elderly Medicare beneficiaries have some form of Medigap coverage;
- The fixing of the beneficiary deductible at $60 from 1973 through 1981 has largely been responsible for decreasing the total portion of beneficiary payments for deductibles and coinsurance from 32.3% of total expenditures for physician services in 1968 to only 20.8% of beneficiary responsibility for these expenditures; and
- Approximately 78% of the aged population in 1978 who received Medicare payments for physician services experienced some liability exceeding the deduc-

tible and coinsurance amounts for unassigned claims, with only about 15% of this population having liability of $100 or more.

Determining Physician Reimbursement Under Medicare

Medicare reimbursement steadily has been diminished over time with various changes authorized by Congress to reduce program expenditures. For example, there has been a substantial reduction in reimbursement brought about by the application of the economic index in fiscal year 1976.

The economic index has caused and continues to reduce Medicare reimbursement for physician services in comparison with other payment mechanisms as it uses the prevailing charge level in effect on June 30, 1973 (which by virtue of a statutory time lag reflects 1971 actual charges) as the base year figure for setting the index. The index is also based on statistical data that fail to reflect actual increases in the costs of providing medical services.

Since the initial application of the economic index, the AMA has consistently pointed out that its limiting effects have been a significant reason why physician charges have in many instances exceeded the Medicare-allowed level. The economic index has served to almost double the percent of "general practitioners" who had customary charges exceeding the prevailing charge limit for office visits, according to an Urban Institute study conducted pursuant to a grant from the Health Care Financing Administration (HCFA) in 1981. If the economic index had not been in place and the prevailing charge was allowed to rise to reflect normal charges, only 25% of the practitioners would have exceeded the prevailing charge level in 1978, and this figure would have actually decreased to approximately 23% in 1980. With the arbitrary limits of the economic index in place, 43% of the general practitioners in the study group had customary charges that exceeded the prevailing charge for limited office examination visits in 1978, and this figure rose to over 46% in 1980. Directly as a result of the existence and application of the economic index, nearly an additional 20% of the "general practitioners" in the study group exceeded the prevailing charge level in 1978 and an approximately additional 25% exceeded this level in 1980. According to the study, general surgeons, internists, orthopaedic surgeons, and ophthalmologists had similar patterns for office visits.

Physician Reimbursement Options Under Medicare

There have been many proposals in recent years to modify physician reimbursement under the Medicare program. The AMA has reviewed these proposals, and we will discuss our concerns about some of them.

Freeze in Physician Reimbursement

On March 7, the American Medical Association sent a letter to every physician in the country urging each to voluntarily freeze his or her fees for a one-year period and to continue to take into account the financial circumstances of each patient—especially the unemployed, the uninsured, and those under Medicare—and to accept reduced fees when warranted. In a November 1, 1983 letter to all members of the House of Representatives, the AMA has pledged to ask physicians to refrain from passing additional costs to their elderly patients, and to urge all physicians to be considerate of the needs of their patients and to avoid increasing the financial burdens of their patients.

In calling for an across-the-board freeze of physician fees, the AMA is asking physicians to contribute to a resolution of the economic problems facing our health care system. While all of the segments of the health care system have contributed to the increases in health care costs, physicians are now going to take a positive step to arrest this trend through the voluntary one-year freeze in their fees. With the overall economy as a whole in far better shape today than it was even one year ago and with inflation no longer continuing to grow annually in double digits, the AMA believes that a vast majority of physicians will heed the call to voluntarily freeze their fees.

The voluntary freeze proposed by the AMA applies to all physicians and includes charges to physicians' patients that are covered by Medicare. We also believe that this step will be especially helpful in easing the current deficit problems facing the federal government, as the action taken by the AMA is in line with a one-year freeze of Medicare payments to physicians as proposed by the President in his recent budget.

Mandated Assignment for Physician Services

In our opinion, the current system where physicians have the option to accept assignment on a claim-by-claim basis has been used properly, and it should be allowed to continue. Of the nearly 90% of physicians that treated some Medicare patients in 1982, approximately 70% of those physicians accepted some claims on an assigned basis. Also, the percent of physicians who do accept some assigned claims has actually increased from over 61% in 1978 to the approximate 70% figure in 1982. The Medicare program has allowed physicians who do not accept assignment on all claims to charge patients in addition to the Medicare "reasonable charge" in recognition of the facts that the Medicare program is not intended to be a welfare program; that it fails to reimburse physicians at the usual, customary or reasonable charge; and that the reimbursement mechanism should encourage physicians to participate in the program. In the development of the Medicare program, Congress considered these matters in giving physicians the option to bill directly or accept an assignment.

Because physicians have a choice to accept or not accept assignment, Medicare beneficiaries are in turn able to select a physician from virtually the entire physician population. A change in the assignment policy, especially in light of proposals to further hold down Medicare

Part B reimbursement, could affect the access of Medicare patients to the physician of their choice. Indeed, a paper prepared pursuant to a grant from HCFA and published in the Summer 1983 issue of *Health Care Financing Review* indicates that if physicians were placed in a position of having to decide whether to accept all or none of their Medicare patients on an assigned basis that over two-thirds of physicians would take no assignments. This would result in a drastic reduction in assignment rates nationwide.

Physicians consider a number of factors in deciding whether or not to accept assignment on a particular claim: the nature and expense of the service provided, past payment experience with the Medicare carrier, the ability of the individual patient to pay for care on a par with non-Medicare beneficiaries, and the relationship between the physician and the patient. This last factor is particularly important, as it raises the point that patients should discuss whether they (patients) have a need for the claim to be submitted on an assigned basis prior to the initiation of the billing process. Statistics clearly point out the fact that most physicians are willing to accept assignment of some claims.

Examples of charges substantially higher than the Medicare recognized charge are the exception and not the rule. Indeed, physicians treat many Medicare beneficiaries at a reimbursement level that is significantly below the usual and customary level of reimbursement. The following statistics for 1979 (generated by HCFA) detail the record of physician acceptance of Medicare assignment.

In 1979, 51.1% of all claims (aged and disabled beneficiaries) were assigned, and 50.7% of the total charges were assigned. Breaking these statistics down further, assignment rates increase in situations where average annual charges per user increase. While the percent of total charges that were assigned for aged Medicare enrollees equalled 46.5%, this figure steadily increases as total annual charges per user increases.

Total Annual Charges Per User	*Assigned Charges As A Percent of Total Charges*
$1-99	29.5%
100-149	28.8%
150-199	32.5%
200-249	34.6%
250-299	36.2%
300-349	38.0%
350-399	40.0%
400-499	41.6%
500-699	44.4%
700-999	46.1%
1000-1499	46.6%
1500-1999	46.2%
2000-2499	48.5%
2500-and up	54.3%

The percent of services assigned and the percent of total charges assigned similarly increase as beneficiaries grow older. This is particularly significant as Medicare reimbursement for physician and other medical services increases with age.

Age	*Reimbursements Per Enrollee*	*Percent of Services Assigned*	*Percent of Total Charges Assigned*
65-69	$187	43.7%	44.4%
70-74	$213	44.6%	45.5%
75-79	$241	47.3%	47.9%
80-84	$253	51.0%	51.2%
85 and up	$260	59.4%	59.2%
Average Total	$219	47.9%	48.3%

Responsibility for charges in situations where physicians do not accept assignment under Part B rests with beneficiaries. While individual examples can be pointed out about beneficiaries with large outstanding liabilities for services, the statistics clearly illustrate that most individual beneficiaries are not being faced with high levels of personal liability for physician charges.

While it is reasonable to expect that the great percentage of Medicare beneficiaries have some unassigned claims (78%), the personal liability exceeding the deductible and coinsurance amounts for 83.9% of Part B service users was less than $100 on unassigned claims. It should also be noted that total user liability for Part B services includes mandated co-insurance and the Part B deductible ($60.00 in 1979). For those individuals who used Part B services in 1979, 64.9% of them had a total user liability of less than $150 each. The following chart sets out total user liability for individuals receiving Part B services in 1979.

*Amount of Total User Liability**	*Average Co-Insurance Liability***	*Total Percent of Those Submitting Claims*	*Average Reimbursement*
$0-50	$11	16.6%	$44
$51-75	$14	15.5%	$57
$76-100	$24	15.3	$95
$101-150	$45	17.6%	$178
$151-200	$78	8.9%	$311
$201-250	$112	5.6%	$447
$251-300	$145	3.7%	$579
$301-400	$191	5.0%	$762
$401-600	$270	5.4%	$1079
$601-and up	$514	6.4%	$2055

*Including co-insurance and $60 deductible.

**These figures are based on the assumption that average reimbursement is 80% of the Medicare recognized charge.

The American Medical Association believes that the figures set out above show that the medical profession has an exemplary history of treating Medicare beneficiaries on an assignment basis. In addition, Medicare fees for physician services have been subjected to arbitrary reductions through prevailing fee limitations and the application of the economic index.

The existing system where physicians have an option to accept or not accept assignment has not resulted in beneficiaries facing substantial out-of-pocket costs as a result of physician charges above the Medicare recognized "reasonable" charge. Indeed, the fact that over 50% of all claims are assigned and that over 50% of the total charges were on an assigned basis in 1979 points to the fact that case-by-case determinations on the acceptance of assignment allows assignment decisions to be molded to fit the individual situation. Furthermore, the figures for acceptance of assignment have been steadily increasing: in 1982, 52.8% of all claims were on an assigned basis, and 54.2% of total charges were assigned.

Participating Physicians

Another proposal relating to acceptance of Medicare assignment that has been under discussion is the "participating physician" concept. Under this type of proposal, physicians who agree to accept assignment on all claims for Medicare beneficiaries will be listed as "participating physicians," and other physicians could still be allowed to participate in the program and make assignment decisions on a claim-by-claim basis. Various versions of this concept have been discussed including different levels of reimbursement for participating and non-participating physicians. While such proposals may be attractive on their face, they pose numerous problems. First, the elderly would be given the mistaken impression that only physicians indicated on the list as "participating physicians" would be eligible to provide service for Medicare beneficiaries. It also fails to recognize situations where physicians may accept assignment for a substantial percentage of their Medicare case load while continuing to bill their full charge to those patients in their practice who can afford to pay the full charge.

The fact that the participating physician concept provides Medicare beneficiaries with assignment information on only the percentage of the physician population that will accept assignment in all cases leads us to conclude that this proposal will not result in an overall increase in the assignment rate. Differential reimbursement levels for participating and non-participating physicians ultimately could penalize the beneficiary. The American Medical Association does not believe that a participating physician program should be instituted: the current level of acceptance of assignment appears to be appropriate given the general amount of beneficiary liability for unassigned claims; developing a participating physician program would be administratively complex and expensive; and such a program would offer only minimal benefits.

Reimbursement Incentives

One of the problems with the Medicare program is the paperwork requirement associated with it. To correct this problem, we recommend a series of administrative modifications to the physician billing and payment process that could eliminate some of the paperwork burden. In addition, we believe that billing initiatives could also serve to encourage even greater physician participation in the Medicare program. Some billing initiatives that could be undertaken on an administrative level include:

Multiple-List Claims. Currently, claims must be submitted to Medicare on the basis of one claim for every office visit. If the claims process could be modified to allow for a single claim to account for all services to a patient in a specific time period or to account for services to more than one patient, the paperwork burden could be substantially reduced. This could also lead to fewer claims being processed and administrative savings.

Automated Billing. The technology exists to allow for claims to be electronically submitted and paid. This type of electronic billing and payment procedure would also decrease administrative costs of the program and it would work to increase physician participation by speeding cash flow for Medicare patients.

Periodic Payments. Where Medicare beneficiaries constitute a substantial portion of a physician's practice, a system could be developed where payments accepted on an assigned basis could be made to the physician on a periodic basis in a lump sum based on estimates of the services to be provided over that period of time. While this system would require continual adjustments in such payments, it would act as a substantial incentive for physicians to treat Medicare beneficiaries and accept assignment through its assurance of continual cash flow.

Physician Payments Based on Diagnosis Related Groups (DRG)

Another concept for physician reimbursement that has been discussed is to base payment for physician services on DRGs. This concept is to be the focus of a Congressionally-mandated study from the Department of Health and Human Services (HHS) that is due in December 1985. Pending the outcome of such a study, we believe it premature to consider this modification in physician payment. In addition, we are concerned that such a radical restructuring in payment could be imposed without even limited experiments with such a system. Minimally, demonstration projects with this concept should be conducted to give insight into its very feasibility.

Just as the AMA has concerns over the hospital DRG payment program, we have concerns with a DRG-based physician payment plan. Even if such a plan was feasible, we have grave questions over how it could impact on the quality of care. While we do not expect that physicians would consciously limit the care they provide, a DRG system would give substantial economic incentives to provide minimal care. The DRG methodology of payment also concerns us because of its failure to take into account severity of illness. This fact could be especially troublesome for those physicians who, because of their specialized skill and training, see patients with the most severe illnesses.

We are particularly concerned about a program where all services to hospital inpatients could be based on DRGs and made through the hospital. First of all, physicians with privileges at only one hospital would be at the mercy of the hospital for their reimbursement, and the institution could penalize physicians by providing minimal payments in cases that exceed the average length of stay for any particular DRG. Also, if both hospital and physician reimbursement is based on a predetermined amount, the physician has an economic disincentive to act as the guarantor of high quality health care.

The AMA cannot recommend a reimbursement change based on DRGs without any showing that such a change would be feasible and not detrimental to the quality of health care services.

Long-Term Restructuring of Physician Reimbursement Under Medicare

The American Medical Association recognizes that the Medicare program and the Part A program in particular are heading for a fiscal crisis in the next decade. Accordingly, the AMA Board of Trustees has directed two of its councils, the Council on Legislation and the Council on Medical Service, to develop a program that would help assure the long-term solvency of the Medicare trust fund. In this review of the Medicare program, no aspect is being held sacred and we fully expect to examine the methodology of payment for physician services.

Physician reimbursement methods generally have been the subject of continuing study by the AMA, and further recommendations on this subject will be considered at the Association's June meeting. At this time, the Association maintains that the usual, customary and reasonable methodology for determining payment for physician services should be viewed as just one mechanism to assure payment for services, and that experiments should be conducted on alternative methods such as voluntary vouchers to pay for health care services, including physicians' services. The Association is also examining potential program changes that could result in having more physicians accept the Medicare reimbursement as payment in full for all lower income beneficiaries.

Conclusion

The American Medical Association is committed to the provision of the highest possible quality of care for Medicare beneficiaries. To assure the viability of this commitment into the future, the AMA is now midway through the process of reviewing the Medicare program with an eye toward assuring its very existence into the next decade. The AMA is proud of the role physicians have played in treating the millions of Medicare beneficiaries over the last eighteen years. We firmly believe that these beneficiaries generally have received high quality services from physicians at appropriate costs. We fully expect that this record will continue into the future.

MASSACHUSETTS MEDICAL SOCIETY'S antitrust lawsuit against Blue Shield was supported by the AMA Board of Trustees. The trustees voted to file an amicus curiae brief defending the medical society's March 19 victory against the state plan. Chief Judge Andrew A. Caffrey of the U.S. District Court, Boston, ruled that Blue Shield's ban on balance billing was an illegal restraint of trade. Blue Shield has appealed the decision. Attorneys for the medical society predict that the case will go to the U.S. Supreme Court. The lawsuit arose out of a long-standing dispute between the society and Blue Shield about the carrier's prohibiting physicians from billing subscribers for amounts over and above their "usual and customary" reimbursement. MMS charged that Blue Shield had placed caps on the amounts by which charges may increase in any given year. The medical society argued that the ban on balance billing amounted to illegal price fixing. In Massachusetts, Blue Shield does not pay subscribers if they obtain services from non-participating physicians, according to a board report. Judge Caffrey concluded that, because of the insurer's large share of the market, physicians were forced to accept its pricing terms to maintain a viable practice in the state.

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Parental Rights Versus Government Responsibility for Infant Medical Care

WM. BRADFORD REYNOLDS

I am pleased to be with you today and to participate in this important and timely policy conference on "Parental Rights Versus Government Responsibility for Infant Medical Care." Few issues are as difficult or as emotionally charged as the question of what medical measures ought to be taken to save the life of a newborn child who, irrespective of life-preserving medical treatment, is expected to be incurably handicapped in his or her future life.

In the first instance, the question poses a moral dilemma, to be analyzed and answered by each individual according to that individual's values and beliefs. But, as the title of today's conference reflects, the question also poses a broader issue of public policy—a civil rights issue that, in the end, must be resolved through application of the community's shared values—that is, by application of laws. It is to this dimension of the question I would like to address my remarks today.

Federal law prohibits recipients of federal financial assistance from discriminating against individuals on the basis of handicap in any federally-funded program. Under this law, Section 504 of the 1973 Rehabilitation Act, nourishment and medically beneficial treatment may not be withheld from handicapped infants solely because of their present or anticipated mental or physical impairments.

It has been suggested that federal inquiry into whether a hospital, as a recipient of federal financial assistance, has discriminated against a handicapped infant by failing to require the performance of life-preserving care or medical procedures must end if the infant's parents refuse to consent to such care or procedures. Indeed, that was the thrust of the district court opinion of Judge Wexler in the *Baby Jane Doe* case that is presently on appeal in the Second Circuit. As long as the hospital is following parental instructions in declining to perform the procedures in question—so the theory goes—the hospital cannot be guilty of any discrimination, since its staff cannot legally perform surgery or other medical procedures upon the child without parental consent. The parents, it is argued, are the only entities responsible for action determining whether the child receives the treatment or medical care in question—that is, by consenting or refusing consent. And, since they are not recipients of federal assistance, the parents are not subject to federal prohibitions against discriminatory behavior or decision-making.

This argument is, in my judgement, seriously flawed from a law enforcement point of view. It unrealistically absolves hospitals of all responsibility and effectively removes Government from its traditional civil rights enforcement role under Section 504. Let me expand on that observation.

It is, of course, true that the performance of a medical procedure upon a child ordinarily requires the consent of a parent or legal guardian. This is so because the law has long recognized the incapacity of children to make certain kinds of decisions for themselves, or to accurately assess their own best interest. The law presumes that parents have not only the capacity to recognize their children's best interests, but the desire to do whatever will best serve those interests. In general, this is an accurate and wise assumption. A parent can usually be depended upon to act in the child's best interests, to the best of the parent's ability to understand and promote them.

Yet, this is not always the case, and state laws generally recognize this unfortunate reality by providing for means of governmental and judicial intervention in cases of parental neglect or abuse of a child. This fact underscores the essential premises on which our laws regarding parent and child are based. Among those premises is the conviction that the individual rights and interests of children, which merit protection in their own

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right, are generally best assured and safeguarded by parents—adults who are well situated and discern those interests and strongly motivated by love to pursue them. Moreover, because of the complex dynamics of family life and psychological needs of children for stability and certainty, the best interests of children are generally served by affording parents substantial authority and autonomy in making decisions affecting their children.

But it is important to note that our law is distinctly *not* premised on a view that a child's rights and interests are necessarily coterminous with those of his or her parents. And a child's rights—at least, federal rights—are certainly not subordinate to or somehow dependent upon those of his parents. To the contrary, children, no less than adults, are independently protected by federal constitutional and statutory guaranties, including the full panoply of civil rights protections.

It is against this backdrop that we must consider the implications of parental consent or non-consent in a "Baby Doe" case. Under some circumstances, parental failure to permit life-preserving medical procedures from being performed on a child may constitute child abuse or neglect under state law. For example, consider a case where, for religious reasons, parents refuse to permit a blood transfusion necessary to save the life of an otherwise normal, healthy child injured in a car accident. Few would question the propriety of a hospital seeking to have such a parental decision overturned by another authority. In all probability, the hospital would seek the intervention of a court to remove the child temporarily from the parents' legal guardianship and authorize the needed transfusion, or would report to the local child abuse and neglect prevention agency, thereby prompting possible government intervention. Indeed, under the laws of most states, the hospital would have a legal responsibility to take some action.

There is no meaningful distinction between this case and many of the cases of handicapped newborns—that is, no distinction except that, in my example, the child is otherwise normal and healthy with every promise of a full and vibrant life, while the "Baby Doe" infant has been born with a disability that portends a life that, in the eyes of some, will be more painful, perhaps much shorter, and certainly filled with monumental inconveniences for all the family.

Let no one misapprehend the significance of this difference. In most cases, it translates into two very different lifestyles—a difference in economic burden, in emotional strain, in responsibilities assumed and undertaken, and in just plain work.

But this reality, notwithstanding its potentially overwhelming consequences in some circumstances, is not one of which the law, or those charged with its enforcement, may properly take cognizance. For the law establishes basic rights and protections for "individuals"—for "persons"—terms that are not defined or limited with reference to age, infirmity, or incapacity.

One of these most basic rights is to enjoy the protection of the laws to an equal extent as other individuals in society. Can there be any doubt, then, that a child, no matter how young or how severely handicapped, has a claim of right to the protection of state laws prohibiting child abuse and neglect on an equal basis with any other child? Part of this protection lies in state law provisions aimed at third persons, such as medical professionals, charged with reporting responsibilities when confronted with instances of possible child abuse or neglect, and with the obligation to aid in the prevention of such conduct. Another part is lodged with the courts that are empowered to override parental decisions in certain situations.

It is thus not sufficient to use parental consent as an excuse for withholding recommended medical treatment. Even in the absence of the parent's consent to medical procedures necessary to save the life of a "Baby Doe," a hospital retains a responsibility to initiate appropriate action through child welfare agencies and, if need be, in the courts, to override parental authority—in precisely the manner that it would proceed under my earlier hypothetical, where the parents denied consent for a blood transfusion needed by an injured but otherwise normal child.

This being the case, a parental decision to withhold consent to a medical procedure needed to save the life of a handicapped newborn does not alone pretermit the opportunity for federal inquiry. The possibility still exists for the hospital to act discriminatorily towards that child. Its choices are, quite clearly, to respond to the parental decision with silent acquiescence, or to take action by seeking outside review of that decision by appropriate authorities. Silent acquiescence may well be proper in some situations, depending on the severity of the disability and available medical treatment for the infant's condition. But if the hospital's decision not to invoke outside intervention to override the parental decision is based solely on the fact that the child suffers from mental or physicial handicaps, then this choice is discriminatory and legally prohibited in the context of federally-assisted hospital activities.

There is another reason that a parental decision to withhold consent to a medical procedure does not resolve the question of whether a hospital's federally-assisted activities are being carried out free from discrimination based on handicaps. A treating hospital and its staff can have an enormous influence upon the outcome of parental decision-making. As I observed earlier, parents can generally be expected to act in their children's best interests—to the extent of their ability to undrestand and promote those interests. But to what extent can the parents of a severely handicapped newborn accurately assess their child's true circumstances? Their assessment, of course, and whatever decisions they may make regarding medical care for their child, must necessarily be based on the information and advice provided to them by medical professionals. It would certainly be possible for a hospital to effectively discriminate against a handicapped child through the advice and information given to parents regarding their child's condition and prognosis.

I do not intend to suggest here that the substance of bona fide medical judgments is subject to governmental review or should be considered discriminatory because they communicate a negative prognosis. I do maintain, however, that protection of handicapped infants from invidious discrimination demands that bona fide medical judgments be the basis of treatment decisions, and not personal biases of involved medical personnel, or others, regarding "quality of life." And, under Section 504, the bona fides of the medical judgment on which parental decisions have been based may be an issue open to investigation by federal authorities.

Perhaps an example will help to illustrate the point. One of the most publicized cases of a handicapped "Baby Doe" was that of a Down's Syndrome child born in Bloomington, Indiana. The parents of that child refused to consent to surgery upon the child's esophagus, surgery without which the child could not receive life-sustaining nourishment. The obstetrician who first advised the parents as to their child's condition and prognosis described Down's Syndrome children as in many cases "mere blobs." He told them that while most Down's Syndrome children could eventually learn to walk and talk, their speech generally consists of at best single word—that Down's Syndrome children are quite incapable of communicating what they feel and sense, and cannot attain even a minimally acceptable "quality of life."

This information can hardly be considered an expression of bona fide medical judgment. It represents a vast departure from any acceptable professional standard of accuracy in the prsentation of well-established information and clincal experience. Yet, I think we can safely assume that this initial description of the child's future strongly influenced his parents in their decision to withhold consent to life-saving surgery. The child, after six agonizing days, died of starvation.

The point is that there are, indeed, instances in which hospital staffs who advise distraught parents are in fact responsible to a considerable degree for the decision to let an infant die. Given this reality, a hospital should not be able to raise parental non-consent as an impenetrable shield to all inquiry regarding the hospital's role in determining the treatment of an infant patient submitted to its care. As we assert in the *Baby Jane Doe* case in the Second Circuit—and at this stage in the case this is all that we assert—access to hospital records should be allowed in order to permit the claim of discrimination to be investigated. That is, I submit, the absolute minimum protection that this handicapped infant is entitled to under Section 504.

In closing, I want to share with you part of one of the many letters I and the Attorney General have received from private citizens respecting the issue of treatment for handicapped newborns. A women who now works with handicapped children wrote that she was diagnosed at birth as brain-damaged, and given a prognosis in terms of potential and quality of life similar to that which has been given to Baby Jane Doe, the New York child with spina bifida and other afflictions. This women has taught for several years and is in the process of earning a second graduate degree. She had this to say:

> The most crucial issue underlying this case is what value an individual life has. In our society, there is a strong tendency to value a person for what [he or she] can do; and the goals of child rearing, education, and training often center on eventual productivity. When such a value system is in force, people who cannot be very productive in the traditional sense of the term tend to be regarded as being less valuable, less important, and less deserving of the rights afforded to "productive people." Doctors are just as susceptible to adopting a productivity personal value perspective as anyone else, but a doctor's professional status does not make such a perspective more legitimate. The documents proclaiming rights in this country—the Declaration of Independence, the Constitution of the United States, etc.—do not specify that a person must be "productive" to have equal rights.

It is, I think, important that this observation be kept in mind in our deliberations on this most difficult issue. It is equally important to recognize—as this letter and this woman's personal experiences illustrate—that our predictions of human potentialities, even when based upon the best available medical information and advice, are far less than certain. By assuming facts of which we cannot possibly be certain, by too quickly stopping short in our inquiry as to human worth, and by not always fully appreciating that the full measure of legal and human rights belong s well to those infants born with the most severe of handicaps, we may, perhaps, succeed in simplifying some of our own tasks and responsibilities. But, it is certain that we will in that process lose much that is valuable in our society, and inexcusably compromise the integrity of our most cherished legal principles. It is, therefore, imperative, in my judgment, that the Government's efforts on behalf of the Baby Does in our society not be abandoned.

Month in Washington

Congress Passes Fee Freeze—With Sanctions

With virtually no substantive debate, Congress on June 27 approved a rigidly-monitored 15 month physician fee freeze expected to save Medicare $2.9 billion over the next three years.

The provision, attached to the FY85 budget bill, would require federal monitoring of every physician who did not sign a "participating physician" agreement. It would provide financial inducements for physicians who signed "participating physician" agreements committing them to assign all claims thereby accepting the frozen Medicare fee allowance as payment in full.

Nonparticipating physicians would be federally monitored. If a pattern of increasing fees to Medicare patients during the freeze was found, the physician could be fined up to $2,000 or "debarred" (suspended) from Medicare for up to five years.

The provision was concocted by Office of Management and Budget Director David Stockman and House conferees Reps. Andy Jacobs (D-IN), Henson Moore (R-LA) and Henry Waxman (D-CA) as a way out of an impasse over Senate resistance to House demands that any physician fee freeze be accompanied by mandatory assignment.

Responding to the committee action, the American Medical Association said that the new program would "intrude into the physician patient relationship for Medicare beneficiaries" and "is discriminatory toward a law abiding segment of physicians" and "patients who want to choose their physicians and have a voice in their own medical care."

The Medicare fee freeze is a major portion of the $6.5 billion in Medicare cuts included in the budget package of spending cuts and tax increaes. Other major Medicare savings came from an increase in premiums and tighter limits on Medicare payments to hospitals. The package was approved 268 to 155 in the House and 83 to 15 in the Senate.

Until the conferees agreed to the new monitored freeze, the fee freeze and the premium increase had been major obstacles to passage of the budget bill. A Senate proposal would have frozen all fees for one year and then continued the freeze for a second year for physicians who didn't agree to accept all claims on assignment.

However, most House conferees were adamantly opposed to a freeze without mandatory assignment and still preferred a previously rejected House proposal tying a fee freeze to mandatory assignment of all inpatient claims. The House conferees wanted, at the very least, to "trigger" a mandatory assignment requirement if certain targets were exceeded.

The Reagan Administration had previously indicated that it would accept mandatory assignment if necessary to get the savings from a fee freeze, and Stockman entered the fracas when it appeared the freeze stalemate might kill the larger budget bill. The Budget director called AMA Executive Vice President James Sammons, M.D., and suggested that the AMA, then assembled for its annual meeting, agree to some form of mandatory assignment.

Bluntly informed by Dr. Sammons that mandatory assignment was a non-compromisable issue, Stockman continued to work behind the scenes, reportedly for adoption of a triggered mandatory assignment. Unyielding resistance to any form of mandatory assignment by Sen. Robert Dole (R-KS) and Senate conferees Sens. Max Baucus (D-MT), Lloyd Bentsen (D-TX) and John Danforth (R-MO) led to the development of the alternative.

It will:

- freeze Medicare customary and prevailing fees for all physicians for 15 months beginning July 1, 1984.
- establish a "participating physician" option for physicians who agree to accept all claims on assignment. Participating physicians could increase their billed charges to Medicare and although the fees they receive will remain frozen, the increased billings will be reflected in future fee screen updates.

Prepared by the Washington, D.C.
Office of the American Medical Association

- permit nonparticipating physicians to accept assignment on a case by case basis but monitor each physician comparing current charges to a three month base period compiled by Medicare carriers.
- fine up to $2000 plus the "overcharge" or bar from Medicare any "nonparticipating physician" found to have a pattern of increasing fees collected from Medicare patients.

Other provisions of the budget package would:

- move up to July 1, 1985 the due date for a report on the "advisability and feasibility" of physician DRGs.
- phase in a permanent national fee schedule for clinical laboratories and for lab services in physicians' offices. The fees would be set at 60% of the prevailing charges for the year beginning July 1, 1984.
- limit increases in Medicare's diagnosis related group reimbursement in fiscal 1985 to the rate of increase in the cost of the marketbasket of goods and services hospitals purchase.
- retain an expiring provision setting Medicare Part B premiums at 25% of program costs. This provision would increase the premium in 1986 to $19.10 a month as compared to $17.70 in current law.
- reject an increase in the Part B deductible.
- increase federal Medicaid payments for some pregnant women and children. The provision is a more limited version of Rep. Henry Waxman's (D-CA) Child Health Assurance (Assessment Program).
- reject an extension of current reductions in federal Medicaid payment to states.
- outline new guidelines for telephone monitoring of pacemakers that would take effect unless HHS issued new guidelines by October 1, 1984; establishing a pacemaker registry within FDA; and requiring HHS to review the appropriateness of Medicare payments to physicians for pacemaker implants.
- call for a physician reimbursement study by the Office of Technology. Objectives of the study—to be completed by December 31, 1985—include suggestions for eliminating payment differences for cognitive and procedural care, increasing incentives for acceptance of assignment, and studying the "advisability or feasibility" of national or regional fee schedules.

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DRGs For Doctors May Not Be So Good, Senators Say

Hasty extension of Medicare's diagnosis related groups pricing system to physicians might be an easy way out for Congress but could have unintended consequences for the health care system, two influential Republican Senators agree.

Addressing a June meeting sponsored by the Government Research Corporation, Sens. Robert Dole (R-KS) and John Heinz (R-PA) suggested that although physician reimbursement changes are clearly called for, extension of DRGs to physicians might not accomplish the desired objectives. And a Health Care Financing Administration official Henry Desmarais, M.D., reported "that his agency is keeping its options open" and, upon the advice of its physician advisory group, is looking at a revised relative value scale as well as extension of DRGs to physician.

Sen. Dole, who chairs the Senate Finance Committee, said he believes his colleagues should wait until they have better data before tackling the physician reimbursement issue. Sen. Heinz, who heads the Senate Aging Committee and serves on the Finance Committee, introduced legislation moving Medicare to negotiated fee schedules for physicians.

Noting that Congress has already directed HCFA to study the "advisability and feasibility" of physician DRGs, Dole reported that the Office of Technology Assessment will also be studying physician reimbursement and that his committee is working with the Institute of Medicine to assure than an IOM physician reimbursement study is useful to Congress. He urged his colleagues to "wait until all the cards are on the table before we start dealing a hand which can't be played."

Heinz said that extension of DRGs to physicians would mark "a longer step in health care policy than our present knowledge can possibly justify." His bill, introduced June 13 and called the Medicare Incentives Reform Act (MIRA), is viewed as an alternative to a measure introduced by Sen. Edward Kennedy (D-MA) and Rep. Richard Gephardt (D-MO). Like the Kennedy-Gephardt plan, MIRA would encourage the development of state cost control plans applied to all payers. Whereas Kennedy-Gephardt relies on the threat of a federal all-payers DRG plan to induce state action, the Heinz measure would increase Medicare payments to states that set up their own plans. States that did not would be subject to tightened-down Medicare hospital DRG provisions and to a new Medicare physician payment system.

Unlike the federal portion of the Kennedy-Gephardt plan which would extend DRGs to inpatient physician services, Heinz in proposing Medicare fee schedules based on a relative value scale that "reemphasizes primary and preventive care and deemphasizes hospitalization and high technology." To become fully operational in 1990, the fee schedule would be accompanied by a requirement that participating physicians take all inpatient Medicare claims on assignment and by regional limits on increases in Medicare payments to physicians.

Heinz is also proposing to add catastrophic coverage to Medicare and to limit annual out-of-pocket costs to two $200 annual deductibles—one for hospital services and one for physician services. The new coverage would be financed through an annual premium projected at $193 in 1985. The intent is to eliminate the need for insurance supplementing Medicare.

In defending his and Sen. Kennedy's proposal before the same meeting, Rep. Gephardt described the plan as one which allows states to pursue either the competition or the regulatory approach.

"The jury is out" on the relative merits of the two approaches, he explained, so Kennedy-Gephardt is an "attempt to drive us closer to both results at the same time. It sets goals and lets states pursue them whichever way they want, but it is important that we set the goals."

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HCFA Ratchets Down on Hospitals

Increases in Medicare payments to hospitals next year would be held to about 4% under new regulations to be proposed by the Department of Health and Human Services.

Although one portion of the formula used to calculate payments under Medicare's diagnosis related groups would be increased by 5.6%, another of the factors that determine the payment is being decreased by 2.4%.

HCFA officials said that as a result overall Medicare payments to hospitals will increase by 4.2% next year. Hospital officials said that the regulation will mean that the increase per payment will be 3.2% to 4% and that hospitals will receive about $1 billion less than they would have been paid if their earlier understanding that rates would be increased by 5.6% had held up.

The permissible rate increase is included in proposed regulations to update the prospective pricing system which took effect last October. Although HCFA intended to issue annual updates of the DRG rates and regulations by June 1, the regulations still were not published in the Federal Register at month's end.

Part of the delay was attributed to a behind-the-scenes battle between hospitals and the Reagan Administration over the rate increase to be permitted next year. Strict application of the updating formula in the DRG law would have resulted in an increase of 7-8%. HCFA officials were considering an increase of only 2-3%, however, based on another provision of the law that required that payments under the new system be budget neutral—i.e., no greater than—those under an earlier targeted payment system.

Hospitals complained that HCFA had misconstrued the budget-neutral requirement payments after 1986. HCFA then announced it would permit DRG base rates to increase by 5.6% next year.

At the same time, however, the agency made a 2.4% across-the-board reduction in the weights of the DRGs. Since a hospital's payment for any given case is ascertained by multiplying the weight of the DRG for the particular case by the base rate, the agency had in effect held the increase to a much lower level.

The change, according to a HCFA official, was necessary because the hospitals upgraded the severity of the conditions they recorded as the principal diagnosis last year by more than HCFA thought they would. In other words, he agreed, there was more "DRG creep" than anticipated.

"Whether this is gaming (to circumvent the system), or whether the hospitals are just doing a better job of assigning" the diagnosis, "I don't know," he added.

Hospitals charged that the new rates are unfair to hospitals which have made a good faith effort to implement the new payment system. American Hospital Association Executive Vice President Jack Owen viewed the new rates as a "slap in the face to hospitals and physicians who tried to make the prospective system work." Federation of American Hospitals director Michael Bromberg threatened to go to the courts or Congress to redress the situation.

* * * *

First PRO Contract Signed

On June 21, the South Carolina Medical Care Foundation signed the first peer review organization contract in the nation.

The peer review organizations (PROs) will monitor the care provided hospitalized Medicare patients. They will replace the professional standards review organizations (PSROs), which since 1972, had performed similar duties.

The South Carolina Foundation also functioned as a PSRO and was reported to have turned in one of the best PRO bids in the country. Its $3.68 million contract is effective July 1 and will run for two years.

* * * *

Health Cost Information Proposal Assessed

Arguing that accurate data on health care costs and quality is a necessary ingredient to control of health care costs, a coalition of groups representing employers, unions and the elderly is pushing for wider dissemination of such data in general and of an amendment sponsored by Rep. Ron Wyden in particular.

The Wyden amendment, which has been scaled down from an earlier version attached to a health care technology bill, would direct the Public Health Service to use existing resources to study current efforts by business and others to collect and interpret health care data. The department would then be required to provide technical assistance, upon request, to consumer or purchaser groups that want to create their own data bases or to better understand data available from other sources.

Now part of a health manpower bill approved by the House Commerce Committee, the measure is intended to encourage the development of data collection efforts around the country. It does not authorize the PHS to collect or disseminate comparative price and quality information, however. Nor does it require providers or insurers to provide any data to the groups trying to assemble it. Confidentiality of individual patient records is to be "assured."

Groups such as the American Medical Association, which opposes the Wyden provision, have maintained that "the purchase of health care services is unique and does not necessarily lend itself to easy comparison based on price or comparative utilization." They further argue that while the bill attempts to protect the individual patient, "there have been problems in the past with careless dissemination of" such information.

Groups which favor the Wyden amendment respond that consumers are capable of understanding the data. They see the Wyden measure, which one supporter characterized as "benign," as a first step to other efforts to make health care price, utilization and quality data more widely available.

Many of the same groups are also pushing for the new peer review organizations (PRO) that will monitor the care Medicare patients receive. The proposed PRO regulations would make data on specific hospitals available but would protect data on individual physicians. Hospitals and physician groups have argued that the proposed regulations are too broad. The business and consumer groups, which want physician specific data to be available to the public think they are too restrictive.

At a press conference June 13, Wyden said he expects his measure to come to the House floor within "the next few weeks." The proposal as yet has no Senate sponsor. In the House, it has also been endorsed by Commerce Committee chairman Rep. Henry Waxman (D-CA), Rep. Richard Gephardt (D-MO) and Rep. Tom Tauke (R-IA).

Tauke's home state last year created the Iowa Health Data Commission which has issued two reports. One reported wide variations in hospital charges across the state for 25 frequent diagnoses; the other compared financial statistics of hospitals over the period 1977 to 1982. It is that type of data that the proponents of the Wyden amendment want to foster.

Five groups represented at the press conference included the American Association of Retired Persons, the AFL-CIO, and the Washington Business Group on Health. Their primary argument involved the need for better data in a more competitive health care system.

* * * *

The Blues Restrict Coverage

In a year, the Blue Cross and Blue Shield Association will begin restricting its coverage of X-rays, CAT scans, and other diagnostic imaging procedures it believes to be medically unnecessary.

The use of diagnostic imaging procedures escalated 8% this year, and is expected to continue to climb. Many procedures are misutilized, overutilized, or redundant, said Blue Cross and Blue Shield Association President Bernard R. Tresnowski in June.

When a procedure is medically necessary and is justified in writing by the physician, the Association will pay for it. When medical necessity is in question, the case will be reviewed by a committee of Blue Cross and Blue Shield medical advisors. If the doctor and committee disagree, payment will be denied.

"Generally, we will pay the claim. But we'll be asking a lot more questions," said Tresnowski. The key recommendations of the guidelines are:

- Neither thermography nor diaphanography are recommended to evaluate suspected breast cancer or other breast disease.
- A CAT scan should not be used to evaluate minor headaches, but may be indicated in the case of unusual headaches suggesting a more serious brain disease.
- Ultrasound should not be used during pregnancy unless a specific problem is suspected.
- Routine chest X-rays are not recommended for any situation, including prenatal visits, hospital admissions or employment, except on the basis of individual history and physical examination or in testing for specific diagnosis.

Seven professional medical organizations participated in the development of the guidelines: the American College of Radiology, American Academy of Pediatrics, American College of Nuclear Physicians, Society of Nuclear Medicine, American Academy of Neurology, and the American Association of Neurological Surgeons.

* * * *

Cancer Breakthroughs Near, Congress Hears

Intense research into cancer and oncogenes now appears to be on the brink of producing actual clinical applications. Within a decade, scientists predict that they will be able to screen patients, more precisely classify tumors, and even offer therapy using this fledgling technology.

At a June hearing of a House Science and Technology Committee Subcommittee, researchers from the nation's top research institutes presented some of their most optimistic prediction yet.

By the year 2000, the current 50% cancer survival rate will jump to 75% with better preventive measures and up to 90% when oncogene research is applied, said Dr. William F. Feller of Georgetown University.

Using oncogenic know-how, new tumor classification techniques should be available by 1986; improved tumor diagnosis, by 1990; and actual cancer therapy, by 1994, said researchers.

Oncogene probes can identify the genetic changes that signal a cancerous or at-risk individual. Because the probes can identify oncogenes, and even pinpoint where they are being expressed, very early cancers can be detected. This will be especially useful in diagnosing cancers in hard-to-reach organs, such as the pancreas, scientists said.

Improved tumor classification techniques will also be a boon to patient management. The presence of a specific oncogene may be predictive of a certain tumor type and behavior. This is important to clinicians who need to know which tumors will respond well to aggressive chemotherapy and which tumors will be unaffected.

Oncogene research funds are growing at twice the rate of other basic research funds. Oncogene investigations comprised 3.7% of the total National Cancer Institute budget in 1983, then doubled to 8.4% in 1984. A similar climb in funding is expected in 1985.

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AIDS Blood Test Nears

Five companies have been chosen by the Department of Health and Human Services to develop a blood test for AIDS based on the virus discovery announced in May. These companies have been given the HTLV-III agent that has been called by researchers as the most likely candidate yet to be the cause of AIDS. They will produce it in quantity for antibody testing of HTLV-III in blood from patients with AIDS and others.

Development of the test is being monitored by the Food and Drug Administration's Blood Products Division—not as usually is the case with tests by the Medical Devices Division. This is supposed to ensure that besides the development of a test that works with some predictability, effort will be devoted to finding out what it means when an individual is antibody positive and what effect testing blood for transfusion for this virus and its antibody will do to the nation's blood supply.

* * * *

Drug Manufacturers Release Cost Study

The Pharmaceutical Manufacturers Association produced a cost-effectiveness study showing that a number of drugs when properly used are the least expensive forms of treatment for disease and overall substantially reduce costs of health care. Examples cited were glaucoma, preventing heart attacks, anti-ulcer therapy.

The study was the result of three years of work the PMA said. The findings, considering the source, are not particularly surprising. But the effort should be noted, this study is yet another move in a trend in the health care field—efforts to determine what's cost-effective and what isn't. Everyone's asking "what is the best buy?," and the health care field is no exception.

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FDA Calls For Warnings on Chymopapain

The checkered career of the enzyme chymopapain has received yet another setback. In the 18 months since the FDA approved this meat tenderizer for treating herniated discs, at least five patients have died and 28 others had adverse reactions when given chymopapain injections for disc lesions.

The finding prompted the Food and Drug Administration to get the manufacturers to send out a warning letter to physicians and issue a labelling change emphasizing the hazards. Not clear is whether the problems arose because the agent wasn't used properly or whether they are intrinsic to the therapy. Chymopapain digests protein and some patients had spontaneous aneurysms.

Guidelines and Perspectives on the Utilization of Intravenous Therapy in Skilled Nursing Facilities

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ABSTRACT—This decade marks the beginning of the geriatric era—one with a dramatic increase in the number of elderly and a need for providing specialized health care. In response to current health trends and policies for treating the aged, skilled nursing facilities (SNFs) must examine practical and humane approaches for delivering more comprehensive care. The implementation of intravenous (IV) therapy within SNFs would be a rational pursuit in this direction.

The guidelines suggested herein are designed to assist SNFs in expanding their level of care to offer IV therapy. The first steps in organizing a successful IV therapy program require correct procedures and policies to cover training, implementation, in-service education, medical supervision, and quality assurance. Staffing and the division of responsibilities are other important considerations in building a sound organizational structure. We focus on basic procedures of the day-to-day aspects of IV therapy, so that our recommendations will be meaningful to a wide range of SNFs, regardless of size, location and resources.

Introduction

The over-65 population now numbers 26 million and is rapidly growing. There is a dearth of published data on the quality of medical care for nursing home patients,[1,2,3] although an estimated 20% to 25% of the elderly will spend some time in a nursing home.[4,5] By the year 2000, the number of nursing home residents will reach approximately 2 million,[6] and total days of hospitalization for persons 65 and older are projected to rise from 105 million (38%) in 1980 to 273 million (58%).[7] Therefore, we must plan for this vast increase to avoid overloading our current system.

Cost containment will become a primary concern, as Medicare expenditures are projected to increase from $893 to $2,655 per person by the year 2000, or a total cost increase from $22 billion to $88 billion.[7] Medicaid health costs are also expected to rise from $271 per person in 1978 to $806 per person by the year 2000, or a total cost increase from $7 billion to $27 billion.[7] Regulations at both the Federal level (via Medicare) and state levels (via Medicaid) restrict or deny reimbursement to skilled nursing facilities (SNFs) for intravenous (IV) therapy. Consequently, nursing home administrators have had little incentive to establish or upgrade these services.

Hospital costs average more than $250 per day. If SNFs could offer appropriate IV therapy at a significantly lower cost rate, both providers and third-party insurance carriers would realize considerable savings. Current reimbursement rates for SNFs vary from state-to-state, but are usually much less than $100 per day. With health care dollars shrinking, more efficient methods are needed to provide for the predicted increase in health needs for the elderly. We propose the following model for SNFs wishing to establish a safe and effective IV program.

At the present time, the quality of care for the acutely ill nursing home patient has been limited by the lack of routine services for IV therapy.

A substantial number of nursing home admissions to general hospitals are due to dehydration[8] with or without accompanying pneumonia or other acute infections. Few SNFs offer IV therapy or specialized acute care units,[9] and at present, the use of clysis often remains the only available treatment for rehydration of patients.

The recent introduction of Diagnosis Related Groups (DRGs), designed to contain hospital costs for patients receiving Medicare benefits, provides an added incen-

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tive for establishing IV therapy in skilled SNFs. Theoretically, it will no longer be cost-effective for hospitals to provide extended care for the elderly if SNFs can deliver the same care at lower costs.

Patients who can be effectively treated at facilities within their own residences could avoid overly aggressive medical workups and accompanying expenses associated with hospitalization,[10] resulting in an added incentive for promoting the concept of advanced care in more SNFs.

Establishing IV services in SNFs would accomplish four main purposes:

1. More hospital beds would be available for more acutely ill patients.
2. Hospital admissions would decrease for SNF patients requiring minimal rehydration or short courses of IV antibiotics that an acute care area can administer.
3. Overall medical costs would decrease because similar care could be delivered at a lower reimbursement rate.
4. The SNF staff could focus more closely on the patient's psychological, medical and financial status in planning for discharge or extended care in an SNF or other facility.

The Acute Care Area

A typical SNF would designate no more than 5% of its beds as an "acute care area" (ACA). These beds would be reserved for any patients receiving IV therapy and would be grouped in an area of the home where sterile technique and isolation would be possible.

The Medical Director or designee would approve all admissions to the ACA, including those for SNF residents needing more advanced health care and appropriate admissions from a general hospital. They would see any patients receiving IV therapy during their rounds.

Once a patient is transferred into the ACA, the Medical Director or designee would assume total responsibility for that patient's medical care. The Medical Director or his designee will order IV fluid type and antibiotics or additives as indicated. Intravenous nutritional support can also be implemented if appropriate.

Appropriate facilities for monitoring electrolytes and determining complete blood counts and basic chemical parameters must be available on a daily basis, provided for by private licensed laboratories. All guidelines and policies would be formally adopted by the Medical Staff of the SNF prior to implementation.

Personnel

The model IV program would have an organizational structure that fosters teamwork and accountability, with committees to oversee utilization review (quality assurance), infection control, and pharmacy services.

Registered nurses (RNs) would have an important role in delivering IV services and will be involved in all aspects of patient care. Qualified RNs will initiate IV therapy, but will consult the Medical Director or physician designee if three attempts fail to establish a patent system. Depending on the facility's needs, specific full-time RNs would be assigned to coordinate and run the IV program. A registered dietitian would also be needed to assess nutritional requirements, including the coordination of any IV nutritional program. Social workers in the SNFs would work with hospital personnel to screen and identify hospitalized patients that could benefit from this program.

Discussion

In proposing these guidelines, we realize that no one SNF is exactly like another and that each is at a certain stage of development. Some SNFs already offer IV services and anticipate expansion; others are just recognizing the need to initiate programs. A SNF's size, location, staff, resources and funding—along with economic realities—will influence the division of responsibilities and level of care. Therefore, our recommendations address the basic considerations—utilization review, infection control, patient education, and pharmacy services—that would apply to all SNFs, regardless of individual differences.

The goals center on safe, effective treatment and meticulous monitoring, a preventive approach to deal with complications and infections, recording of all procedures, and making all patient information immediately available.

High-quality standards can only be achieved through the interdisciplinary skills and cooperation of all staff members.

Recently, the Wisconsin Regional Geriatric Center has advocated the use of specialized nursing units as the best method to deliver quality health care for the elderly.[9] The Center is a 24-bed unit offering elderly patients multidisciplinary care for a variety of illnesses, mostly involving cardiac, gastrointestinal, and infectious diseases.

The ACA concept, as presented here, should not be viewed as an attempt to "hospitalize" the SNF or divert appropriate admissions away from general hospitals. The ACA should be viewed as a transition between the SNF's routine skilled nursing care and the hospital's general medical care. It would focus and coordinate psychological, medical, nursing, and social skills geared to the special needs of a geriatric population. Appropriate allied medical care, such as physical and speech therapy for rehabilitation, would be requested as indicated.

The ACA program would also help prevent "transfer trauma" and the disorientation that can occur when the elderly are uprooted from their environment and placed in a hospital intensive care unit.[11]

Moreover, the ACA concept does not disagree with the concept of "minimal interference," as advocated by Seegall.[12] This stresses that invasive procedures and other aggressive techniques should not be routinely used if they cannot improve the quality of life in the elderly patient. Intravenous therapy provides needed hydration and antibiotics where indicated. The trauma and expense to the patient are minimal, and the potential benefits can be significant. Patients who are felt not to be appropriate candidates for the ACA because of their overall prognosis would not be admitted there.

As further experience is gained with the use of IV therapy in SNFs, the benefits to such patients will become obvious. We believe that implementing IV therapy in SNFs can effectively provide more comprehensive care to the growing number of nursing home patients now and in the future.

GUIDELINES FOR IV THERAPY IN SKILLED NURSING FACILITIES

THE MEDICAL DIRECTOR

- The Medical Director or physician designee should have total and direct responsibility for the IV program, overseeing the ongoing training, evaluation, and in-service teaching of all RNs involved in the program.
- The Medical Director will be appointed by the governing Medical Board of the facility and will have appropriate qualifications to conduct and supervise the IV program, in addition to meeting any appropriate state requirements. The Medical Director would report directly back to this board.
- The Medical Director will complete all continuing medical education requirements as mandated by state law.
- The Medical Board may appoint other physician designees to work under the supervision of the Medical Director. Their qualifications should also allow them to conduct and supervise the IV program and meet other state requirements as appropriate.
- Only the Medical Director or physician designee would be authorized to give written or verbal orders for IV fluids, and all orders must be signed within 24 hours.
- The Medical Director or physician designee must be available on a 24-hour basis for back-up support and supervision of all patients receiving IV therapy.
- The Medical Director or his physician designee shall clearly document on the patient's chart the reason for IV therapy and outline the specific treatment or course.
- The direct administration of any bolus medication via an IV line must be done by the Medical Director or physician designee.
- All IV solutions, drugs, or other additives will only be selected from the list of substances approved by the Pharmacy Committee and Medical Board.
- The Medical Director may make emergency additions to the list of approved drugs, additives, and solutions and apprise the Pharmacy Committee of the changes.
- The Medical Director or physician designee may issue orders for IV services, solutions, drugs, or other additives for patients receiving IV therapy at the time of admission.
- The Medical Director will be responsible for coordinating IV policy with the appropriate facility committees.

REGISTERED NURSES

- All RNs assigned to maintain IVs will report to the Director of Nursing or the RN supervisor of the IV program. The designated RN supervisor must be appropriately qualified and appointed by the Medical Board.
- Other designated RNs will be assigned to establish and run a patient education program on IV treatment, and will report to the RN supervisor of the program.
- Other designated RNs will serve as liaisons to the Utilization Review and Infection Control Committees. Their responsibilities are outlined under "Quality Assurance."
- IV fluids and lines will be maintained by currently licensed RNs who must be in the facility whenever IV therapy is administered.
- All RNs who provide IV therapy will have completed a structured course that includes lectures, practical experience, and testing by appropriately trained instructors. This comprehensive training will enable the RNs to understand the physiologic basis and appropriate treatment for possible complications with IV therapy, including infection.
- All RNs will have demonstrated technical competence in the aseptic insertion, regulation, and use of all IV needles, catheters, tubing systems, IV fluids and additives, and Buretrols, including the recognition of any product contamination.
- All RNs in the program will maintain appropriate continuing education requirements, as outlined by the Medical Director and state requirements.
- RNs will be encouraged to attend appropriate outside seminars and meetings to keep abreast of new technology and programs.
- RNs will understand the interaction of all IV drugs being administered and how to reconstitute or prepare the ordered medication or additive and recognize incompatible admixtures.
- All RNs will be able to interpret routine laboratory values used in monitoring patients on IV therapy (electrolytes, arterial blood gases, and other specific

body fluid components). They must notify the Medical Director or physician designee whenever laboratory tests yield abnormal values.

- The Medical Director and Director of Nursing will establish a system of supervision and continuing in-service education requirements and will maintain records of all training, supervision and evaluation.

INTRAVENOUS FLUIDS, SYSTEMS, AND DRUG ADDITIVES

- The Medical Director, Director of Nursing for the facility, and Pharmacy Consultant will compile a list of approved drugs, additives, and solutions for use. This list will be approved by the full Pharmacy Committee and then the Medical Board, and updated at least annually.
- The Medical Director may temporarily use an unapproved drug, additive, or solution, but will inform the Pharmacy Committee at its next meeting.
- All orders for IV therapy will be given in writing, when possible, and will include the correct dosage, time, method and rate of administration, and any special criteria to be followed.
- Buretrols will not be used routinely, to eliminate the possibility of IVs "running dry" and infusing air into the patient.
- Dates of insertion will be clearly marked on all IV systems.
- All IV administration sets will be changed every 24 hours and when any new IV cannulas are inserted.
- All IV solutions will be used within 24 hours of reconstitution or opening.
- All orders for IV therapy will automatically expire every 24 hours unless renewed by the Medical Director or physician designee.
- All medication and fluid errors will be reported immediately to the Medical Director or physician designee, and then to the Pharmacy Committee for review and follow-up.
- Orders to "keep line open" will be unacceptable.

EQUIPMENT

- A list of appropriate equipment to maintain the IV program will be compiled by the Medical Director and Director of Nursing.
- The RN supervisor will be responsible for accounting and maintaining inventory.
- Indwelling IV systems (needles, catheters) will be changed every 48 hours unless a reason is documented on the chart.
- A new needle or IV cannula should be used for each attempt at establishing a patent system. The smallest needle or cannula that will deliver the ordered solution or treatment should be used.
- A stocked IV tray should be available at all times. It should include all required catheters, tourniquets, alcohol pads, IV administration sets, labeling pens, antibacterial packets, sterile 4 x 4 sponges, labels for IV solution additives, scissors, and paper or micropore tape. This tray should be checked daily.
- Appropriate IV poles, approved IV solutions, and arm boards should be available from a central location on a 24-hour basis.

ADMINISTRATION OF IV THERAPY

- Patients receiving IV therapy will be monitored hourly by the RN for possible complications, system failures, and correct rate of administration.
- Any complications of IV therapy—no matter how minor—must be reported immediately to the Medical Director or physician designee and documented on the patient's chart. Medical treatment ordered for the complication will be also documented.
- Any signs of infection will be reported to the Medical Director or physician designee, documented on the chart, and reported to the Infection Control Committee for evaluation.
- The Pharmacy Consultant will make recommendations on all appropriate literature, charts, and reference materials that RNs must have available at all times.
- If possible, the pharmacy dispensing all approved fluids, drugs, and additives should be available on a 24-hour basis for phone consultation.
- The Director of Nursing or a designee will maintain a permanent central recording of all patients who have received therapy. Patient information will include clinical indications, length and type of therapy, and any complications.
- Accurate records will be maintained on the patient's chart. The information will include:
  1. Date IV therapy was started, replaced, or terminated and by whom.
  2. Date and time IV cannula and administration sets were started, replaced, and terminated and by whom.
  3. Type and size of indwelling device inserted.
  4. Type of solution administered and name of preparer.
  5. Total volume and infusion rate of all drugs, fluids, or other additives given during each shift and each 24-hour period.
  6. All complications at site of indwelling catheter.
  7. Any antibacterial agent and dressing applied to site.
  8. Any complications.
  9. Any patient education.

QUALITY ASSURANCE OF IV THERAPY

- A Utilization Review Committee will have the ongoing responsibility of reviewing and documenting the safety and effectiveness of the facility's IV therapy program.
- This Utilization Review Committee will meet monthly and forward recommendations and suggestions on the IV program to appropriate committees.
- The Utilization Review Committee will be appointed by the Medical Board.
- A Quality Assurance nurse, appointed by the Utilization Review Committee, will be responsible for:
  1. Developing research protocols, collecting and analyzing data, and making recommendations to the entire Committee.
  2. Identifying and resolving problems associated with the IV program.
  3. Working with the Director of Nursing or RN supervisor of the IV program to assess effectiveness and resolve problems.
  4. Submitting monthly written reports for review by the Utilization Review Committee.
  5. Working with the RN involved with patient education.
- An Infection Control Committee will be responsible for monitoring and identifying all infections associated with the IV program.
- The Committee will appoint an RN to serve as Infection Control Nurse.
- The designated Infection Control Nurse will:
  1. Create and implement surveillance programs to determine rates of infection (nosocomial and other) throughout the facility.
  2. Develop a system for detecting and reporting all infections associated with the IV program.
  3. Establish appropriate control methods to act on infection-related problems that develop in the program.
  4. Report to the full Infection Control Committee on rates of infections, infection sites, treatments instituted, and results.
  5. Develop criteria to be followed when patients receiving IV therapy have clinical symptoms of sepsis.
- A Pharmacy Committee will be responsible for monitoring all solutions, drugs, and additives used in the facility.
- The Pharmacy Consultant will serve on this Committee, and be responsible for reviewing the proper dispensing and use of all drugs, additives, and solutions.
- The Committee will:
  1. Compile lists of approved solutions, drugs, and additives that will also be endorsed by the Medical Board. The Committee will review and update that list at least once a year.
  2. Distribute references on IV incompatibilities to floors that provide IV therapy.
  3. Review the circumstances surrounding all drug and solution errors for follow-up and recommendations.

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Physicians' Involvement with Medicare

AMA CENTER FOR HEALTH POLICY RESEARCH

In recent years, the rate of increase in expenditures on health care has received a great deal of attention. Nowhere is this more evident than with the Medicare program, which in 1982 accounted for $52.2 billion (or 16 percent) of the nation's health care expenditures. The Medicare hospital insurance trust fund is predicted to go heavily into debt sometime during the next decade, and substantial efforts are being made to restrain the program costs of Part B of Medicare, or supplementary medical insurance.

Concern over Medicare expenditures has already led to a number of changes in the program. The most dramatic change is a shift in the reimbursement for hospital services from a cost-based approach to a prospective pricing system based on diagnosis related groups (DRGs). Further initiatives may also be proposed for the Medicare program in the future.

Changes in Medicare may have different impacts on various segments of the physician population, depending upon location, specialty, and other factors. Therefore, this report not only examines the overall extent of physicians' involvement with Medicare patients, but also the degree to which this involvement varies among individual physicians. Specifically, information is present on:

- the average share and distribution of Medicare patient visits among physicians; and
- the distribution of visits for Medicare and non-Medicare patients by practice setting.

The data are drawn from the AMA's Fourth Quarter 1983 Socioeconomic Monitoring System (SMS) survey.

Physicians' Visits with Medicare Patients

Table 1 presents the average share of physicians' visits that are with Medicare patients. For all physicians, Medicare accounts for just under a third of total visits. This average indicates the importance of the Medicare program as a payor for physicians' services. The shares of Medicare visits are approximately the same for various practice settings. In particular, 26.0 percent of office visits and 30.6 percent of hospital rounds are with Medicare patients.

Table 1 also indicates clear differences among specialties. Medical specialists have over 40 percent of their total visits with Medicare patients, compared to less than 30 percent for those physicians in general and family practice and the surgical specialties. This difference is evident in both office visits and hospital rounds. However, there is little regional variation in the percentage of physicians' visits that are with Medicare patients.

The differences among specialty groups indicate that the importance of Medicare visits in individual practices can vary. A more detailed depiction of this variation is presented in Figure 1. This figure indicates that for about half of all physicians, Medicare patients account for 25 percent or less of total visits. However, Figure 1 also shows that for approximately 22 percent of physicians, Medicare patients account for 50 percent or more of total visits. Thus, changes in the Medicare program

Table 1

AVERAGE SHARE OF WEEKLY VISITS WITH MEDICARE PATIENTS BY SPECIALITY AND REGION: FOURTH QUARTER 1983

	Share of Visits with Medicare Patients		
	Total Visits [1]	*Office Visits*	*Hospital Rounds*
ALL PHYSICIANS [2]	30.0%	26.0%	30.6%
Specialty			
General and Family Practice	28.0	24.1	28.8
Medical Specialties	43.9	36.7	45.6
Surgical Specialties	25.7	24.4	27.7
Region			
Northeast	33.3	29.0	33.1
North Central	30.8	25.2	31.4
South	27.8	24.8	28.4
West	29.0	25.4	30.5

[1] Includes visits in emergency rooms, outpatient clinics and at all other locations.

[2] Excludes psychiatry, radiology, anesthesiology and pathology.

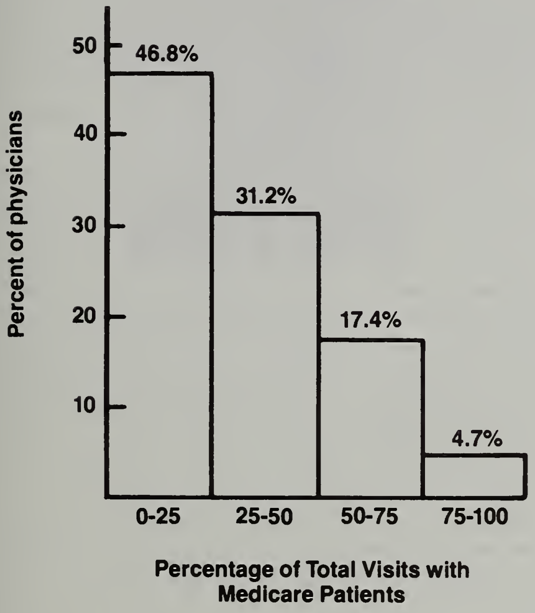
SMS Report, May 1984, Vol. 3, No. 3. Reprinted with the permission of The AMA Center for Health Policy Research.

The AMA Center for Health Policy Research directs the Socioeconomic Monitoring System in cooperation with the AMA Division of Survey and Data Resources.

DISTRIBUTION OF PHYSICIANS BY PERCENTAGE OF TOTAL VISITS WITH MEDICARE PATIENTS: FOURTH QUARTER 1983

Figure 1

All Physicians*



*Excludes psychiatry, radiology, anesthesiology, and pathology

Figure 2

Medical Specialists

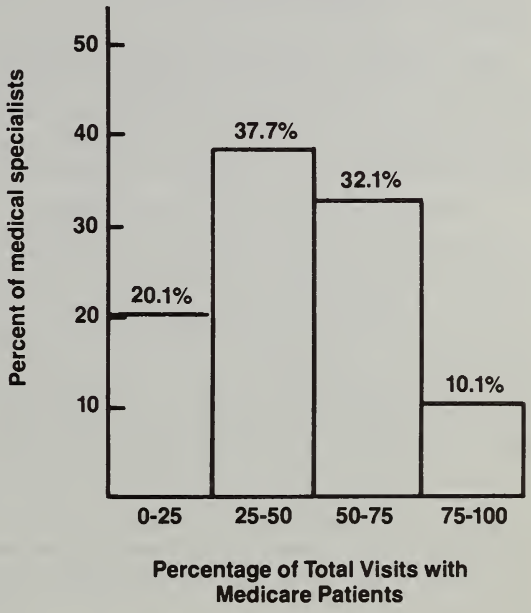


Table 2

DISTRIBUTION OF VISITS FOR MEDICARE AND NON-MEDICARE PATIENTS BY PRACTICE SETTING: FOURTH QUARTER 1983

	Medicare Patients			*Non-Medicare Patients*		
	Office	*Hospital*	*Other Settings*[2]	*Office*	*Hospital*	*Other Settings*[2]
ALL PHYSICIANS[1]	56.8%	28.4%	4.1%	63.4%	24.6%	0.6%
Specialty						
General and Family Practice	64.5	19.3	10.1	79.6	13.2	1.0
Medical Specialties	44.1	42.3	3.7	53.0	36.5	1.0
Surgical Specialties	64.7	30.1	1.4	65.3	28.4	0.1

[1] Excludes psychiatry, radiology, anesthesiology, and pathology.

[2] Other settings explicitly include nursing homes, convalescent homes, and extended care facilities. The percentage of visits do not sum to 100 percent because visits in the emergency room (ER) are omitted.

might have relatively little impact on many physicians, but for a substantial segment such changes could affect the major portion of their practice.

For most of the major specialty groups, the distribution of physicians by their degree of involvement with Medicare is similar to the distribution in Figure 1. That is, more than half of general and family practitioners and surgical specialists have 25 percent or less of their total visits with Medicare patients. However, a much different picture is presented for physicians in the medical specialties.

Figure 2 indicates that only 20.1 percent of medical specialists have practices where Medicare accounts for 25 percent or less of patient visits. Furthermore, for 42 percent of physicians in these specialties, Medicare patients accounted for half or more of their total visits.

Distribution of Visits by Practice Setting

A report from the federal government on Medicare's prospective pricing system for hospital care stated that the ability of a hospital to respond to prospective pricing incentives would depend on the ability of the hospital administration to transmit those incentives to admitting physicians. If pressures are placed on physicians to change their methods of practice in a hospital setting, then some shifting in practice settings may occur. The Socioeconomic Monitoring System has therefore begun to collect information on Medicare and non-Medicare visits by type of setting, in order to monitor any possible changes that may occur in the future.

Table 2 indicates that for all physicians 56.8 percent of Medicare visits are in the office, while 28.4 percent are in the hospital. However, physicians in the medical specialties have a substantially higher proportion of their Medicare visits in a hospital setting than do other physicians. This comparatively high percentage may suggest that physicians in the medical specialties will be more likely than other types of physicians to be affected by pressures created by DRGs. At present, these patterns of visits by practice setting are similar to the pattern displayed by non-Medicare patients.

In summary, there is substantial variation in the degree to which physicians are involved with Medicare. While some physicians have little or no contact with Medicare patients in their individual practices, a substantial number of physicians have practices that are predominantly oriented toward Medicare recipients. In particular, those physicians in the medical specialties have both a higher overall level of involvement with Medicare patients, and a higher level of involvement in a hospital setting.

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The President's Page

A Personal Experience

During the month of June I travelled to Chicago as part of the Connecticut delegation to the AMA House of Delegates Meeting. As a non voting member I was in no hurry to get there and upon arriving at the meeting was both surprised and amused by my initial contacts with other attendees.

My amusement stemmed from the amount of politicking being done by the candidates for various AMA offices and their supporters. This feeling of amusement changed over the next two days as I witnessed the vigor and commitment of the supporters to their candidates as well as their reasons for support which were varied and based not only on geography but upon the firm conviction that a particular candidate will do a better job in office. At times the politicking took on the air of a presidential convention which I found enjoyable and refreshing.

My surprise came when I attended the deliberations of the reference committees and the House of Delegates. Having attended many scientific as well as socioeconomic meetings in neurosurgery I expected more of the same, namely, some people listening and learning with others on vacation. I have never seen a more knowledgeable and articulate group of doctors at any meeting previously, and moreso, I have never been to a meeting which was better attended. Each participant carried literature which looked like the Hartford phone book and from listening to the speakers it became obvious that they were familiar with the subjects discussed. Rarely did one see an empty delegate's seat which was not filled with an alternate when the House was in session.

Reference committee meetings were open to all and all points of view, across the entire political spectrum were aired.

In the House, debate was lively and it was readily apparent that a great deal of work had gone into formulating positions of state and regional delegations, yet, individual opinions were welcomed and heard in a free and open fashion—an example of democracy in action. No group or individual dominated the proceedings and the constant theme remained the welfare of our patients.

The only disturbing theme that emerged had to do with the fact that AMA membership needs to be increased because all physicians were benefitting from the action of this great organization whether members or not. There was some anger expressed about "freeloaders" who share the benefits without paying their fees. Although this is true, recriminations do not solve the problem. We must start now and set aside our biases which may be long standing and look at the facts of life in 1984 and beyond. Erosion of patient care should be our greatest concern. Intrusion into this area which has brought the greatest health care system in the world to all Americans, which cares for all patients regardless of ability to pay, an area which is best served by our profession should not be tolerated. It seems that everyone supports their state society but there is a reluctance to support our national organization. Remember, if the Federal government changes our current health care system for those patients on Medicare or Medicaid it won't be long before State governments are coerced into doing the same under the guise of improving the system, but, in reality, the changes which will occur are concerned only with cost rather than quality.

Forget your biases, prejudices and preconceived ideas about your national organization—join the AMA—we're on your side.

Joseph S. Sadowski, M.D.
President

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Reflections from the Dean's Office

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ROBERT U. MASSEY, M.D.

Corpora non agunt nisi fixata
—Paul Ehrlich

Several months ago at a meeting where dealers in used and rare medical books were displaying their wares, I had the good luck to pick up a biography of Paul Ehrlich written by his secretary, Martha Marquardt. In 1923, on the occasion of the seventieth anniversary of his birth, she had written "Paul Ehrlich als Mensch und Arbeiter;" the biography which I found was an extension of that work written by her in English in 1951, with an introduction by Sir Henry Dale.

The story is simply told, warm, full of personal reminiscences, but also fairly comprehensive in its account of Ehrlich's scientific work. It is a *Heldenleben,* the story of a generous, eccentric, and lovable genius.

For my generation it was either Paul de Kruif who introduced us to Paul Ehrlich in *The Microbe Hunters,* or else it was Paul Muni in the movie, *The Magic Bullet.* When we were medical students, Salvarsan, or 606, was no longer medical journalism, but it hadn't yet become medical history; it was about as far in the past for us as the work of James Watson and Francis Crick is for the present generation of medical students. Arsphenamine is gone, but the concepts which Ehrlich brought to immunology and pharmacology were powerful paradigms which have guided much of the research down to the present time.

He shared the 1908 Nobel Prize for Medicine with Eli Metchnikoff for their work in immunity. It was Metchnikoff who had been converted from zoology to pathology after seeing free-floating mesodermic cells in transparent starfish larvae engulf the tip of a rose thorn which he had introduced. He was on vacation in Sicily; his family had gone to the circus, and he, just poking around, evoked and observed a phenomenon which changed his life and began the research which led to an understanding of the reticulo-endothelial system. *Fresszellen* he called the cells—phagocytes. "From that day forth I was a pathologist."

Ehrlich, too, was poking around, only his interest was in staining tissues with aniline dyes. His doctoral thesis had been on histological staining techniques; from his observation that each dye had specific cellular affinities, he conceived the idea of specific receptors which would dominate all of his work for 40 years.

Martha Marquardt tells a story about Ehrlich's early school days in Breslau. He had done well in Latin and mathematics but had had terrible problems with German composition. One day the students were asked to write an essay on the subject, "Life—a Dream." During the oral examination which followed, the headmaster had difficulty understanding the meaning of young Paul's composition, and asked him to explain what he had written.

> "Paul, distressed and confused, began to stammer. 'Yes, ... wissen Sie, verstehen Sie ... life *is ... re vera ... a chemical incident ... a normal oxidation* and the dream ... the dream is *a flourescence of the brain,*' he finished quickly."

Ehrlich's side chain theory and his concept of receptors was at first proposed to explain the biologic specificity of dyes; he later extended it to the lock-and-key specificity of the antigen-antibody reaction. His studies in immunity using plant proteins as antigen led to collaboration with Emil von Behring who had been working with diphtheria and tetanus anti-toxins. According to Marquardt, it was Ehrlich's method of preparing diphtheria anti-toxin which led to a serum rich enough in anti-toxin to be clinically useful. Von Behring took the credit and the profits, and the collaboration fell apart; the enmity between the two lasted until Ehrlich's death in 1915.

The notion of specificity in stains and antibodies led to the idea that chemical agents could be found or developed which would have specific "parasito-tropic" qualities. He began with a benzidine dye, trypan-red, and had good results with experimental trypanosomiasis in animals. Another substance, Atoxyl, the original organic arsenical, had been used by Thomas in 1905 to treat trypanosomiasis. Bertheim, in Ehrlich's laboratory, worked out the proper formula for this substance, arsanilic acid, and with it the long, arduous experimental work began which led ultimately to the first successful treatment of syphilis and the first effective chemotherapeutic agent.

Ehrlich's work shows the power of a sound concept in directing a lifetime of fruitful research. Marquardt's biography argues that intelligence, imagination, and personal integrity were equally essential to successful scientific work. For Ehrlich, success lay in the "big G's": *Geduld, Geschick, Geld,* and *Glück*—patience, ability, money, and luck.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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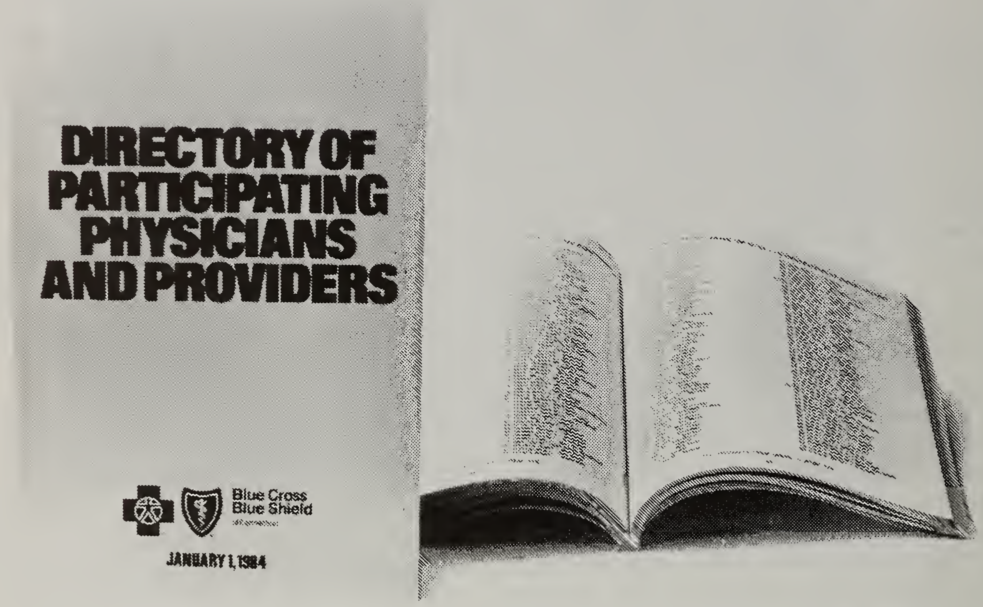

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Editorials:

Who Should Make Medical Decisions?

Publication of Mr. Reynolds' remarks on the provision of care to severely handicapped newborns in this issue of *Connecticut Medicine* represents an explicit statement of the current Reagan administration's position on the complex set of issues identified under the nomenclature of "Baby Doe."

As appropriate for a representative from the U.S. Department of Justice, the statement represents a legal analysis of a very complex medical question and, I believe, demonstrates the limitations of this approach. Legal analysis is essentially retrospective and based either on the precedent of common law or interpretation of the provisions of a legislative statute. There is little room for accommodation of scientific and medical progress, let alone for the ambiguities of medical judgment and decision making. The latter is heavily influenced by estimates of ultimate outcome, an innately subjective process heavily dependent upon a practitioner's past experience, training and awareness of scientific progress, particularly as it pertains to a specific disease or group of patients.

Good medical judgments are also influenced by an appreciation and understanding of the emotional, social, economic and environmental circumstances in which decisions are to be made. It is precisely this humanistic aspect of medicine that the profession is frequently accused of forsaking in the practice of an impersonal brand of scientific medicine.

This is the aspect of medical decision-making that Mr. Reynolds denigrates as reflecting "personal bias" when he insists that the government has a role in protecting the civil rights of handicapped infants. To the extent that these decisions do not reflect the application of up-to-date medical knowledge, he has a valid point. It is essential that improved systems for scientific communication and provision of timely expert consultation be brought into the process.

It is wrong however to suggest that medical decisions can somehow be reduced to a quantitative formula by which correct and incorrect decisions can be defined. I suspect that this concept derives from the inappropriate application of the reasoning process used in law. The legal profession has the benefit of precedent as well as the explicit language of law. It is required not to make estimates of the future but rather to interpret actions and decisions of the past and apply them to the present. (Here, too, Mr. Reynolds appears to be wrong. In May 1984 U.S. District Judge Charles Brieant ruled that section 504 of the 1973 Rehabilitation Act was invalid since it was never intended to apply to the care of newborns.)

Finally, it is somewhat disingenuous to insist the federal government is merely asserting its right for review of the medical records in order to determine if discrimination occurred. The very nature of such a request with its attendant intrusions significantly impacts the ordinary activities of a hospital and intensive care nursery. Moreover it probably alters the behavior of medical professionals wishing to avoid future intrusions upon their time and energies in response to a bureaucratic inquisition, no matter how noble the intensions. Dr. James Strain, while President of the American Academy of Pediatrics, very graphically reported the impact of federal investigative procedures which took place at two well respected tertiary care centers in March 1983, after promulgation of the original "Baby Doe" regulations (New Eng. J. Med. 309:443-444, 1983). It is noteworthy that no evidence of discrimination or of inappropriate denial of medical care was uncovered in either of these two situations, nor, so far as I am aware, in any of the 49 "Infant Doe" cases cited by the administration in publication in the Federal Register

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Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

on January 12, 1984, of the final rules relating to Health Care for Handicapped Infants. These are the very same rules which were struck down by Judge Brieant's decision.

Assuredly medical judgments and the medical decision-making process are not perfect, certainly not when judged in retrospect. As a profession we have probably oversold the notion of medicine as "science" rather than "art" and have too readily encouraged the public to believe in our individual and collective omnipotence. Thus the attitude expressed by government officials—that medical decisions in complex uncertain situations can be defined in objective absolute alternatives—can be partially attributed to our own failure to communicate the subjective and uncertain elements of this process.

Certainly this process can be improved, especially in complex life-threatening situations such as those represented by imperiled severely handicapped newborns. One mechanism is the development of internal hospital review committees, a concept recommended in May 1983 by the outgoing President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and promoted as Infant Bioethics Committees by the Academy of Pediatrics. The composition, scope and authority of these groups continues to engage much discussion and controversy. Even so, the problems posed by provision of care to handicapped newborns are miniscule when compared to problems encountered in the care of adults with terminal illness, especially the elderly. All of these are very difficult and complex questions for which no simple solution exists. These are important problems for study, discussion and resolution by all relevant segments of society, including the medical profession, but they are not likely to be aided by transformation to a legal issue.

Myron Genel, M.D.

Professor Pediatrics
Yale University School of Medicine

AIDS—An Update

The incidence of AIDS in Connecticut, compared to New York and California, is still relatively low with a total of 50 reported cases over a four-year period. It is interesting to note that only one of the cases occurred in the Eastern half of Connecticut while 36 cases were reported from Fairfield county alone, pointing to New York as the likely source of the spread into Connecticut.

Some of the erstwhile mysteries of this new disease have been solved. AIDS is now accepted to be a viral infection, it probably emanated from Central Africa where the rate of prevalence is much higher than in this country. The virus seems related to others found in monkeys, and the human strain may well be a mutation of the agent, invading a new host. In Africa there is no epidemiological link to either homosexuality or to drug use.

Nationwide, the rate of increase of newly reported cases has slowed down slightly, and public concern, as evidenced by interest of the media, has fallen off. The vast majority of those affected by the epidemic continues to be male homosexuals and I.V. drug users, with close to three-quarters of the cases in homosexual or bisexual males and over 20% in I.V. drug users. A small percent does not fit the pattern. The number of drug users is actually larger than the figures might indicate since there is some overlap of homosexuals and drug users and they are counted only once—as homosexuals.

We know, by now, somewhat more about prevention. There has already been some change in lifestyle among homosexual males as a result of the high risk among those who have multiple sex partners. Certain measures, such as the closing of bathhouses, will serve to reduce the rate of new infections. I.V. drug use is difficult to curb but, since it is known to be a definite risk, it can, theoretically, be controlled. A third risk factor—the agent's presence in blood to be transfused—will be brought under control when lab tests are ready to indicate the presence of such agents. Progress in developing such a test is well advanced.

Several years experience with AIDS has shown that overt, symptomatic cases do not pose a problem to those caring for them. It is speculative, though not unreasonable, to assume that by the time the secondary invading organisms create the alarming picture of advanced AIDS cases, the original infection destroying an individual's immunity, may have long subsided. Thus, we are dealing not with patients carrying the virus, but with sequelae of an earlier infection that produced the loss of immunity.

The cough of patients with pneumocystis carinii pneumonia or the diarrheas are not *the* disease, but sequelae. Failure to find any cases among the thousands of health workers, friends and relatives of AIDS cases caring for them, offers assurance that even close contact with such patients presents no risk. Blood of the symptomatic may no longer be infectious at these late stages since no transmissions have occurred to health workers even after needle sticks. However, before this assumption is accepted as definite fact, it is advisable to follow the strict precautions currently in use, as suggested by CDC.

Hans H. Neumann, M.D.

Wilton, CT

in Brief

A summary of AMA, medical & health news

Fortune 500 companies have been informed of AMA programs that are designed to encourage cost-effective quality medical care. In a letter to more than 130 chief executive officers of some of the nation's largest corporations, the AMA outlined the Health Policy Agenda and the Diagnostic and Therapeutic Technology Assessment program, as well as AMA activities in cost-effective care, consumer affairs, and health care coalitions. Response to the mailing has been positive, the AMA said.

The voluntary fee freeze is being supported by 80% of the nation's physicians, AMA President-Elect Joseph F. Boyle, MD, reported. "This doesn't mean that American doctors are simply not increasing their income but that they are losing $9,000-$12,000 a year because their overhead is going up while their fees remain the same," Dr. Boyle told a press conference. The AMA's one-year moratorium will reduce the nation's medical bills by $3.5 million, or 1% of the total, he said.

Hospital medical staff sections have been formed in 14 state medical associations: Alabama, Arizona, California, Georgia, Idaho, Maine, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, New York, Oregon, and Wisconsin. Eleven states are in the process of forming sections: Colorado, Connecticut, Kentucky, Ohio, Oklahoma, Pennsylvania, South Carolina, Texas, Utah, Virginia, and Washington. Copies of the AMA publication, "Guide for Formation of a Hospital Medical Staff Section," may be obtained from the Dept. of Hospital Medical Staff Services, AMA Headquarters.

The AMA Education and Research Foundation mailed checks totaling $1.5 million to state medical societies for distribution to medical schools. The funds, representing many contributions from physicians, their families, and friends, were collected by AMA/ERF during 1983. Most schools received two checks this year. One check was presented to deans for unrestricted school use. The other check is restricted for use in student assistant programs.

The AMA's insurance subsidiary, AMACO, established record growth in both premium volume and total assets in 1983. The American Medical Assurance Company is a participating reinsurer of medical society-created/physician-owned medical liability insurance companies. AMACO has added new accounts each year it has been in business. Today, it reinsures 18 physician-owned companies covering more than 60,000 physicians.

Infant bioethics committees should be educational, not regulatory, the AMA said in response to guidelines proposed to meet requirements in the federal "Baby Doe" rules. According to AMA Board of Trustees Chairman John J. Coury Jr., MD, the AMA "opposes the use of committees as part of any mandated regulatory activity including a civil rights enforcement program." Dr. Coury emphasized that "such mandated activity would undermine the ability of advisory groups to serve their intended purpose of assisting in a most sensitive, complex, and personal area."

Two original paperbacks have joined five earlier titles in the AMA Home Health Library published by Random House. Now available in bookstores are *The AMA Straight-Talk, No-Nonsense Guide to Better Sleep* and *The AMA Straight-Talk, No-Nonsense Guide to Health and Well-Being After Fifty.* The new paperbacks sell for $8.95 each. Three hardcover books have been released in paperback for the first time: updated guides to *WomanCare, HeartCare,* and *BackCare.* Also in print are *The AMA Family Medical Guide* (hardcover) and *The AMA Handbook of First Aid and Emergency Care* (paperback). Discounts are available for bulk mail orders addressed to Random House.

Eight medical societies and their cable TV programming efforts are featured in a new publication from the AMA Division of Communications. Titled "How Cable Works," the booklet includes sections on the use of cable to promote health education, a glossary of "cablespeak," and a history of the medium. Free copies are available from Heidi Hough, Dept. of Consulting Services, AMA Headquarters. The telephone number is (312) 645-4413.

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Council Meeting

Wednesday, June 6, 1984

Organizational Meeting

The organizational meeting of the Council for 1984-85 was called to order by the President, Joseph S. Sadowski, M.D. Following some opening remarks, which included a moment of silence to honor the 40th Anniversary of the invasion of Normandy, and the introduction of Council members, elections of a Chairman and Vice-Chairman of the Council for 1984-85 were held. Those elected: Chairman—Guy W. Van Syckle, M.D., Danbury; Vice-Chairman—Mehdi S. Eslami, M.D., Waterbury.

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahrens, Alisberg, Beck, Bobruff, Bonner, Canzonetti, Concannon, Czarsty, Dardick, Doctor, Freedman, James, Kamens, McDonnell, Mendillo, Orphanos, Petrie, Sadowski, Scheer, Villa and Waldron.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Sweeney, Mr. Tomat (FCMA), Mr. Meister (NHCMA), Mr. Coffey (HCMA) and Mrs. Eslami (President, Auxiliary).

Absent were: Drs. Ahamed, Fabro, Friedberg, Kaess, Ragusa, Reyelt, Jr., Seide, Sweet, Whalen, Jr. and Zlotsky.

Reports from Physicians Serving on State and Federal Agencies

Dr. Petrie reported on a town meeting he attended in Bristol concerning local ordinances relating to control of abortion. He noted that the proposed six ordinances caused heated debate and that he will continue to monitor the situation.

Dr. Abbot reported on the Statewide Health Coordinating Council (SHCC) meeting of May. He noted that much of the meeting centered around health planning activities promoting ways to provide funding for future years. He also remarked on a SHCC staff report on the status of participation by physicians in the Title XIX (Medicaid) program. According to the report the lack of participation in the program appears to be the results of a combination of factors including reimbursement policies, administrative paperwork, and reluctance to provide care to a population whose social environment tends to stimulate recidivism or delay cure. The report also states that OB/GYN care is practically unavailable to Title XIX clients.

After some discussion, which centered around DIM reimbursement policies, Dr. Czarsty noted that the Department of Income Maintenance had a proposal before the General Assembly to increase reimbursement levels on the physician side of the program and to encourage Medicaid clients to utilize physicians' offices instead of hospital emergency rooms. However, the proposal was defeated.

After discussion concerning Dr. Canzonetti's stepping-down from the CPRO Board of Directors, the Council VOTED to appoint Dr. Kamens to that Board. In addition, Dr. Canzonetti provided background information relevant to the Health Care Financing Administration (HCFA) rejection of the CPRO's Request For Proposal. The CPRO RFP will be submitted again during the summer.

Mr. Fiorentino noted that two Health Systems Agencies were now adopting Nuclear Magnetic Resonance Guidelines (NMR) and that the Office of EMS, State Department of Health Services has promulgated a draft of Free Standing Emergency Care Facility Center Guidelines. His staff report was accepted as information.

Report of the President

President Joseph S. Sadowski, M.D., commented on the following items: Referred from the House of Delegates meeting were three resolutions requesting the President and the Council to appoint committees to evaluate and report on the following subjects:

Licensing of Physicians

1. The present methods for physician licensure in Connecticut.
2. The credentialing process utilized by hospitals in Connecticut.

3. The present method of communicating among the states, the status of individuals practicing medicine, with or without a license, in or outside a hospital.

Physician Reimbursement for In-Hospital Care of Patients Prospective Pricing Systems Fee Schedules for Physicians

The following resolution encompassing all three subjects was adopted:

RESOLVED: That the President of the CSMS appoint an Ad Hoc Committee to study and report to the House of Delegates on:

1. The types of reimbursement and payment systems being considered.
2. The impact of these systems on the availability and quality of patient care in Connecticut.
3. The ethical, moral and financial implications of these systems.
4. The alternatives open to the profession in coping with or opposing these systems, including legislative action, and be it further

RESOLVED: That the CSMS oppose legislation linking hospital and physician reimbursement, and be it further

RESOLVED: That the CSMS Council develop strategies to oppose all-payer prospective reimbursement legislation requiring mandatory acceptance of fee schedules for physicians' services.

All-Payers Legislation

That the Council instruct the appropriate committee(s) to institute monitoring of the effects of the All-Payer legislation on the quality of patient care.

The Resolution Re Licensing of Physicians was referred to the CSMS Committee on Hospitals for evaluation and report back to the Council.

The Resolutions Re Physician Reimbursement for In-Hospital Care of Patients, Prospective Pricing Systems, Fee Schedules for Physicians and All-Payers Legislation was referred to an Ad Hoc Committee consisting of the following: CSMS Delegates and Alternate Delegates to the AMA, Eve A. Klipstein, M.D., Manchester, and William T. Pastuszak, M.D., Hartford. The Ad Hoc Committee is to undertake a study as to the implementation of these resolutions and report back to the Council.

All-Payer Legislation

Robert R. McDonnell, M.D., New Haven, discussed the recently passed All-Payer legislation and urged the CSMS to monitor prospective payment developments in Connecticut. The Ad Hoc Committee formed as a result of the resolution passed by the House of Delegates will enable the CSMS to monitor its implementation.

Brain Death Guidelines

It was VOTED to trasmit information relating to the recently passed "Definition of Death" legislation to the CSMS Judicial Committee to develop an educational communication (i.e. Brain Death Guidelines) for distribution to members of the Society.

Report of AMA Health Policy Agenda Advisory Committee

The report of Stewart J. Petrie, M.D., New Haven, on the subject issue was distributed to the Council. His report described AMA Health Policy Agenda activities in medical science, education, health resources, health care delivery mechanisms, evaluation of assessment and control and payment for service. It was VOTED to accept Dr. Petrie's report for information and with commendation.

It was further VOTED that the Council of CSMS urge the AMA to publicize the health policy agenda activities immediately and on a continuing basis.

Seat Belt Legislation

It was VOTED to approve the request of Carl Dila, M.D., (Chairman of the Connecticut Society of Neurosurgeons) to meet with the CSMS Committee on Legislation in order to help promote mandatory seat belt legislation.

CSMS Auxiliary

Mrs. Mehdi Eslami, President of the Auxiliary addressed the Council on Auxiliary activities and urged Councilors to support Auxiliary membership for their spouses. She stressed the importance of working together and mentioned that the Auxiliary was an important, untapped resource of the Society. It was VOTED to refer the matter of joint billing for CSMS & AMA Auxiliary dues to the CSMS Fiscal Subcommittee for study.

DRG Validation

It was VOTED to accept the AMA report on the subject for information. According to Department of Health and Human Services, despite the wording of the DRG Validation statement, physicians are not expected to know the ICD-9-CM coding system or how to assign diagnosis-related groups. "Basically, the requirement for physician attestation simply extends to Medicare the long-established practice of requiring the physician to sign the face sheet of the medical record." HHS is preparing a new draft regulation to clarify that the physician is only attesting to primary and secondary diagnoses and major procedures, and is not responsible for the coding.

The issue will be discussed at the forthcoming AMA Convention in Chicago.

Life Members

It was VOTED to receive for information the list of Life Members which is as follows:

Name	Town	Effective Date
William C. Billings	New Haven	1/1/84
Egidio A. Fulchiero	Niantic	1/1/84
Edwin H. Mulford	Norwalk	1/1/84
John J. Murphy	East Hartford	1/1/84
Joseph N. Russo	West Hartford	1/1/84
John K. Shearer	Waterbury	1/1/84
James T. Smith	Torrington	1/1/84
Constantine Veremakis	Brookfield	1/1/84

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on June 6, 1984. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

Chickenpox Vaccine Safe for Leukemia Patients

Children with leukemia in remission may be safely and successfully immunized against varicella, commonly called chickenpox, even if they are receiving chemotherapy, suggests a study reported in a recent issue of the *Journal of the American Medical Association.*

Anne A. Gershon, M.D., of New York University Medical Center, and colleagues immunized 191 children susceptible to chickepox who had leukemia in remission. The researchers report serological evidence of an immune response in approximately 80 percent of the children after one dose and in more than 90 percent after two doses. Forty-two of them had completed chemotherapy treatment one to 12 months before vaccination; 149 had maintenance chemotherapy suspended one week before and after vaccination. The researchers say the major side effect was a mild to moderate rash, especially among the chemotherapy patients.

Twenty-one of the vaccinated children later had household exposures to varicella or zoster. The attack rate among these children was 18 percent, which is significantly lower than the usual 90 percent rate, the researchers not. "All cases of clinical illness were extremely mild," they say, which was clearly different from cases of varicella among normal children or among unimmunized children receiving chemotherapy for leukemia.

"The severity of varicella in children with an underlying malignant condition receiving chemotherapy is well recognized," the researchers say. Earlier reports suggested that without immunization or antiviral chemotherapy, about 30 percent of children with an underlying malignant condition who contract varicella experience severe symptoms, and at least seven percent die.

The researchers point out that no cases of even moderately severe varicella occurred after immunization in this group of leukemia patients. They add, "Our studies of almost 200 children, most of whom were receiving chemotherapy, strongly suggest that varicella vaccine is safe as well as effective to administer to these immunocompromised persons."

New Members

NEW HAVEN COUNTY

Ali M. Aghamohammadi, Ansonia
Sheila A. Alexander, New Haven
Margaret T. Boron, Seymour
Vincente J. Caride, New Haven
Zeno N. Chicarilli, New Haven
Craig W. Czarsty, Oakville
Mark S. DeFrancesco, Waterbury
Peter T. DiNapoli, New Haven
Mark J. Fagan, Guilford
Lester Feldman, Hamden
Henry Gerad, Waterbury
Simon Gurmarnik, Meriden
Marian T. Hsueh, New Haven
Dale M. Intihar, Waterbury
Robert E. Kenyon, Jr., Meriden
Karen L. Laugel, Watertown
Andrew J. Levada, Waterbury
Zeena A. Lobo, Derby
Gary S. Novick, New Haven
Betty J. Reid, New Haven
Martin Schiff, Jr., New Haven
William C. Scott, New Haven
Jayakata Shetty, Waterbury
Douglas P. Shore, Guilford
Jeffrey T. Stern, Waterbury
Glenn G. Taylor, Waterbury
Patricia L. Wiggins, Waterbury
Paul H. Zimmering, Meriden

NEW LONDON COUNTY

Thomas C. Cherry, Jr., Norwich
Bruce Cooper, Niantic
Ajay I. Dalal, Norwich
Francis P. Halas, Norwich
Nagireddy Kamireddy, Norwich
Jeffrey H. Lane, East Lyme
F. Gervan Mlynarski, New London
Saul D. Neuman, Niantic
Anis Racy, Norwich
Marian N. Sarosi, New London
Jeffrey Seltzer, Norwich
Peter H. Shea, Norwich
David J. Shiling, Norwich
Stanley Solinsky, New London
Eric N. Thompson, Groton
Claire M. Warren, Plainfield

MIDDLESEX COUNTY

Philip DiMenno, Middletown
Geoffrey E. Herter, Middletown
Andrea Schaffner, Middletown
Gordon F. Williams, Middletown

TOLLAND COUNTY

Clifford C. Podewell, Vernon

IN MEMORIAM

AUERBACH, SUMNER R., Tufts, 1963. Dr. Auerbach was an internist in the Fairfield County area since 1971. He was chief of oncology, Bridgeport Hospital and was associated with Oncology Associates of Bridgeport. Dr. Auerbach was a member of the Fairfield County Medical Association, and the Connecticut State Medical Society; died June 25, 1984 at the age of 47.

BIEHN, SIDNEY L., University of Toronto Faculty of Medicine, 1926. Dr. Biehn was a general practitioner in the Fairfield County area since 1928. Before his retirement, he was a consultant in general practice at the Bridgeport Hospital. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 2, 1984 at the age of 83.

ETKIND, MEYER G., University of Maryland Medical School, 1933. Dr. Etkind was a general practitioner in the New Haven County area since 1946. In 1980 the Horeb Lodge of B'nai B'rith chose him for the annual Youth Services Award. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died July 5, 1984 at the age of 77.

HANDLER, MARK S., State University of New York at Buffalo 1971. Dr. Handler was an obstetrician/-gynecologist in the Tolland County area since 1977. He served in the U.S. Military from 1975-1977. Dr. Handler was on the staff of Rockville General Hospital. He was a member of the Tolland County Medical Association and the Connecticut State Medical Society; died June 8, 1984 at the age of 38.

HASSAN, KAMAL A., Alexandria University, 1952. Dr. Hassan was an obstetrician in the New London County area since 1967. A former diver for the Egyptian Olympic Team, he participated in the 1948 and 1952 Olympics. Dr. Hassan was a staff physician at Stamford Hospital, St. Joseph's Hospital and Lawrence and Memorial Hospitals. He was a member of the New London County Medical Association and the Connecticut State Medical Society; died June 5, 1984 at the age of 59.

MCLEAN, T. SMITH, University of Vermont, 1934. Dr. McLean was an obstetrician in the Fairfield County area since 1935 and until his retirement, was on the Staff of the Bridgeport Hospital for almost 50 years. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died May 25, 1984 at the age of 75.

MIGNONE, JOSEPH, Yale, 1933. Dr. Mignone was an internist and cardiologist in the New Haven County area from 1938 to 1968. He was assistant chief and chief of medicine at the Hospital of St. Raphael from 1950 to 1954 and president of its staff from 1967 to 1968. Dr. Mignone also was director of ambulatory services at St. Rapheal's from 1968 to 1976 and assistant clinical professor of medicine at Yale University School of Medicine from 1950 to 1976. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died July 5, 1984 at the age of 75.

RICCITELLI, MARIANO, Yale, 1922. Dr. Riccitelli was a general practitioner and cardiologist in the New Haven County area since 1924. He was a professor emeritus at the Yale University School of Medicine and served in the Army Medical Corps during World War I. Dr. Riccitelli was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died July 1, 1984 at the age of 88.

SLATER, DANIEL, New York Medical School, 1940. Dr. Slater was a general practitioner in the New Haven County area since 1946. He served in the U.S. Military from 1942-1945. Dr. Slater served on the staff of Yale-New Haven Hospital. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died June 23, 1984 at the age of 70.

WAKEMAN, EDWARD T., Yale University School of Medicine, 1922. Dr. Wakeman was a pediatrician in the New Haven County area since 1926. He was a physician to the Foote School for more than 50 years and physician to the Children's Center in Hamden for 50 years. Dr. Wakeman served on the Connecticut Abuse Committee. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 17, 1984 at the age of 87.

WEHGER, ROLAND T., Yale, 1932. Dr. Wehger was an orthopedic surgeon in the Fairfield County area since 1934. At the time of his death he was retired from practice. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 13, 1984 at the age of 81.

WEINSTEIN, NATHAN, Trinity College, Dublin, 1934. Dr. Weinstein was an anesthesiologist in the Fairfield County area since 1938. In 1948, he became director of the Department of Anesthesiology, which according to Norwalk Hospital records, he was instrumental in creating. Dr. Weinstein was a former president of the Norwalk Medical Society. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died June 18, 1984 at the age of 79.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Connecticut – Emergency physicians and primary care specialists needed for busy freestanding emergency centers located in Connecticut. Attractive salary and fringes plus early ownership. Send CV to Box 1142, Farmington, CT 06034.

FAMILY PRACTICE

Family Practitioner, Board Certified or Eligible wanted for growing practice in Central Connecticut with one other Board Certified Family Physician leading to partnership. Send Curriculum Vitae to CSMS, FP/JR.

INTERNAL MEDICINE/FAMILY PRACTICE

Physician needed to join as a partner who is either board eligible or certified in internal medicine or family medicine to join an intermediate care center in Waterbury, CT. Please reply to Eastside Medical Center, P.O. Box 365, Cheshire, CT 06410.

INTERNAL MEDICINE

Board eligible/certified internist needed to join a group of 14 internists in a federally qualified pre-paid staff model HMO. A sub-specialty in pulmonary or infectious disease or in allergy is preferred. In our 12th year of service with 37,000 members we are affiliated with Yale-New Haven Medical Center. Excellent pay and a unique benefit package. Submit CV and salary requirements to: Vice-President for Medical Affairs, CHCP, 150 Sargent Dr., New Haven, CT 06511. An equal opportunity employer. M/F.

MISCELLANEOUS

Physicians wanted for New Urgent Care Center in Branford, CT. The Coastline Medical Center, opening August 1, 1984, is equipped with Lab, X-Ray, Defib., etc. Pleasant surroundings. Malpractice insurance provided. Salary competitive. Full or part time. Send resume or phone: H. Ardolino, M.D., River Rd., Essex, CT 06426. (203) 481-0818.

Physician has office space available in the vicinity of The Hospital of St. Raphael, New Haven. For further information call 777-5478.

PEDIATRICS

Pediatrician. Board eligible or certified. Needed immediately for full time position to join an established HMO in Farmington. Doctors form their own independent corporation. Hartford Hospital is primary referral hospital. Contact Eugene Fantl, M.D., Chief, Pediatrics, KFHPC, 99 Ash St., East Hartford, CT 06108 or phone (203) 568-8500 ext. 223.

PRACTICE FOR SALE

Internal medicine. Well established practice available October 1, 1984. Fully equipped office in medical building in Hartford. St. Francis hospital area. Write Physician, P.O. Box 7-516, West Hartford, CT 06107 or call after 6:00 P.M. (203) 521-3991.

Internal Medicine/Family Practice. Unusual opportunity to assume high-profile practice in mid Fairfield County. For details respond to CSMS, PRAC/OPP.

PSYCHIATRY

Innovative, energetic, board certified or eligible psychiatrist desired for this attractive community of 40,000 in Central Connecticut. Economic package offered to help physician establish private practice. Please send C.V. to President, Bradley Memorial Hospital, 81 Meriden Ave., Southington, CT 06489.

PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

ALLERGY

May '84. Age 72. Nat'l bds. AB elig. MD, NY Medical College; Int., Middlesex Memorial Hospital; Res., Institute of Allergies, Roosevelt Hospital. Prefers General Practice, associate or industrial type practice. Available six months out of the year. Contact, Henry Sherwood, M.D., 210 Nehanton St., Apt. 114, Newton, MA 02159.

ANESTHESIOLOGY

January 1985. Licensed in Connecticut. Age 36. FLEX. AB elig. MD, Ein-shams Univ. School of Medicine, Cairo, Egypt; Int., Jersey City Medical Center, NJ; Res., Newark Beth Israel Medical Center, Newark, NJ; Res., Cambridge City Hospital, Cambridge, MA. Prefers solo, group, associate or institutional type practice in a small community. Write, Helmy W. Habek, M.D., 175 Adams St., Apt. 33, Newton, MA 02158.

ANESTHESIOLOGY

July '84. Licensed in Connecticut. Age 34. FLEX. AB elig. M.B.B.S., Delhi University, New Delhi, India; Int., Lady Hardinge Hospital, Delhi and State University of New York at Buffalo, Buffalo, NY; Res., State University of New York at Buffalo. Write, Hansa H. Bhayani, M.D., 95 Scamridge Curve, Buffalo, NY 14221.

July '85. Age 33. Nat'l bds. AB elig. MD, Albany Medical College, Albany, NY; Int., University of Kentucky Medical Center (Surgery); Res., Cambridge Hospital, Cambridge, MA. Prefers group or associate type practice. Write, Howard Feder, M.D., 58 Selkirk Rd., Apt. 16, Brookline, MA 02146.

FAMILY PRACTICE

May '84. Presently in practice. Age 56. MD, University of Bologna, Italy; Int., St. Boniface General Hospital, Winnipeg, Manitoba, Canada; Res., Health Sciences Center, Winnipeg. Prefers group, associate or institutional type practice. Write, Vito P. Girgenti, M.D., 9 Monk Rd., Warwick, RI 02889.

July '85. Age 30. Nat'l bds. MD, University Autonoma of Guadalajara, Malisco, Mexico; Int., New York Medical College and St. Joseph Hospital, Stamford, CT; Res., Somerset Medical Center, Somerville, NJ. Prefers group or associate type practice in a small to medium-sized community. Write, Gerard J. Fitzpatrick, M.D., 1140 L Easton Ave., Somerset, NJ 08873.

FAMILY PRACTICE—Continued

Immediate available. Age 47. FLEX. MD, Catholic Medical College, Korea; Int., University Hospital, NJ (OB/GYN); Res., Psychiatry, Pathology, General Practice, NJ (information available on request). Prefers solo, group, institutional or industrial type practice in a small or large-sized community. Write, Jong H. Kim, M.D., 127 Garfield Ave., Jersey City, NJ 07305.

Oct. '84. Licensed in Connecticut. Presently in practice. Age 48. Nat'l bds. MD, Columbia; Int., Medical College of Virginia; Res., Hartford Hospital; Fellowship, Adolescent Medicine, Children's Hospital, Boston. Desires group practice in a small-sized community. Also would consider Emergency Medicine. Write CSMS, TRA/FP.

FAMILY PRACTICE/PUBLIC HEALTH

Sept. '84. Age 36. FLEX. AB elig. MD, University of Pavia, Pavia, Italy; Int., McGill University, Montreal, Quebec, Canada; Res., Laval University, Quebec City, Quebec and John Hopkins, Baltimore, MD (Public Health). Prefers group, associate, institutional, solo, industrial and academic/research/administrator type practices in a medium-sized community. Write Gabriel Sella, M.D., 320 Niska Rd., Apt. 712, Downsview, Ontario, M3N 2W1, Canada.

INTERNAL MEDICINE

July '84. Age 30. AB elig. MD, M.R. Medical College, India; Int., S.S.G. Hospital, Baroda, India; Res., Bronx-Lebanon Hospital, Bronx, NY. Prefers group, associate or institutional type practice in a medium to large-sized community. Write, Gopal Shah, M.D., 100 Caton Ave., #2G, Brooklyn, NY 11218.

July '84. Licensed in Connecticut. Age 38. FLEX. AB elig. MD, St. George's University, Grenada, West Indies; Int., Bronx-Lebanon Hospital, Bronx, NY; Res., Mt. Sinai Hospital, Hartford, CT. Prefers any type practice. Write, T. Hemmaplardh, M.D., Apt. 1-H, Lathrop Lane, Rocky Hill, CT 06067.

Aug. '84. Age 35. Nat'l bds. AB cert. MD, Medical College of Pennsylvania; Int., Hahnemann Medical College and Hospital; Res., Long Island Jewish Hospital; Fellowship, Nassau County Medical Center and Joslin Diabetes Center. Is seeking an association with an internist/endocrinologist in a large-sized community. Training and subspecialty in pedi-endocrinology and adult diabetes. Write, Constance Stewart, M.D., 99 Pond Ave., D215, Brookline, MA 02146.

GASTROENTEROLOGY. July '84. Age 33. Nat'l bds. AB cert. (ABIM). MD, NY Medical College, Valhalla, NY; Int., Metropolitan Hospital, NY; Res., Metropolitan Hospital and Mount Sinai Services-City Hospital Center; Fellowship, Mount Sinai Services-City Hospital Center, Elmhurst, NY. Desires solo, group or associate type practice in a medium to large-sized community. Write, Neil Tarkin, M.D., 6700 192 St., Fresh Meadows, NY 11365.

Three months notice. Presently in practice. Age 33. Nat'l bds. AB elig. MD, Rush Medical College, Chicago, IL; Int. and Res., Nassau County Medical Center, NY. Prefers group, associate or HMO practice. Write, David R. Carnow, M.D., 3165 Kenwood Lane, Levittown, NY 11756.

CARDIOLOGY. Presently in practice. Aug. '84. Age 36. FLEX. AB elig. MD, Mysore Medical College, India; Int., North General Hospital, NY; Res., Wayne State University, Detroit and North General Hospital, NY; Fellowship, Downstate Medical Center, Brooklyn, NY and Newark Beth Israel Medical Center, Newark, NY. Desires solo, group, associate or institutional type practice in a small to medium-sized community. Prefers Invasive and Non-invasive Cardiology but will do Internal Medicine. Write, Nandakumar S. Iyengar, M.D., 52 Indian Run, Millington, NJ 07946.

GASTROENTEROLOGY. Sept. '84. Age 32. Nat'l bds. AB cert., (ABIM). MD, Albany Medical College, Albany, NY; Int. and Res., St. Louis University Hospitals, Louis, MO, (IM); Fellowship, Washington University Medical Center, St. Louis, MO (Gastro.). Prefers associate, group or solo type practice. Has worked with Physicians Multispecialty Group. Write, Harry D. Burack, M.D., 5548 Waterman Place, St. Louis, MO 63112.

OBSTETRICS/GYNECOLOGY

Immediately available. Age 37. FLEX. AB elig. MB, Topiwala National Medical College, Bombay, India; Res., Long Island College Hospital, New York; Fellowship, Michael Reese Hospital, Chicago, IL (Reproductive Endocrinology/Infertility). Prefers group, associate, institutional or partnership type practice in a medium to large-sized community. Write, Atul Sheth, M.D., 2951 King Dr., Chicago, IL 60616.

ORTHOPEDICS/SPORTS MEDICINE

July '84. Age 35. Nat'l bds. AB elig. MD, Georgetown University School of Medicine; Int. and Res., St. Lukes/Columbia University College of Physicians and Surgeons, New York City, (General Surgery); Mt. Sinai Hospital, New York City (Orthopedics); Fellowship, Cincinatti Sports Medicine. Prefers solo, group, associate or institutional type practice. Write, George McGinniss, M.D., 105 5th Ave. #8E, New York, NY 10003.

OTOLARYNGOLOGY

Aug. '84. Presently in practice. Age 53. FLEX. FRCS. (England). MD, Grant Medical College, Bombay, India; Int., J. J. Group of Hospitals, Bombay; Res., New York Hospital—Cornell Medical Center, NY; Fellowship, NY Eye & Ear Infirmary, NY. Prefers solo practice in a minimum drawing area of 50,000 population. Write, BDP/OTO.

PEDIATRICS

July '84. Licensed in Connectiuct. Presently in practice. Age 31. Nat'l bds. AB cert. MD, Johns Hopkins; Int., Georgetown University Hospital; Res., University of Maryland Hospital and Roosevelt Hospital. Desires primary care pediatric practice, either group or partnership. Also, any non-clinical opportunities. Write, CSMS, PED/SI.

July '85. Age 27. Nat'l bds. AB elig. MD, University of Connecticut, Farmington, CT; Int. and Res., J.W. Riley Hospital for Children, Indiana University, Indianapolis, IN. Prefers solo, group associate or institutional type practice but is obligated to locate in, or service a, National Health Service designated Health Manpower shortage area. Write, A.E. Hertzler Knox, M.D., 7773 Swallowtail Dr., Indianapolis, IN 46224.

RADIOLOGY

Versatile, experienced radiologist available for locum work for 1-4 weeks in Eastern or Central Connecticut. Phone (203) 887-1794.

Oct. '84. Age 60. Presently in practice. Nat'l bds. AB cert. MD, Chicago Medical School; Int., Chicago Hospital; Res., Hartford Hospital, Hartford, CT. Prefers group type practice in a medium-sized community. Interested in a *Part-Time* position. Write, CSMS, RAD/CONF.

NUCLEAR MEDICINE. Presently in practice. Immediately available. Age 38. Nat'l bds. AB cert. MD, Civil Hospital, Ahmedabad, India; Int., Long-Island Jewish-Hillside Medicine Center, NY; Res., St. Vincent's Hospital—NYU, NY (Radiology); Fellowship, VA Hospital, University at Birmingham, AL (Nuclear Medicine). Prefers solo, group, associate, institutional and industrial type practice. Write, Subhash S. Pujara, M.D., Route 3, Box 391B, Andalusia, AL 36420.

COLONEL LEVERETT HUBBARD'S ADDRESS TO THE SOCIETY AT THEIR MEETING FEBy 2d 1784

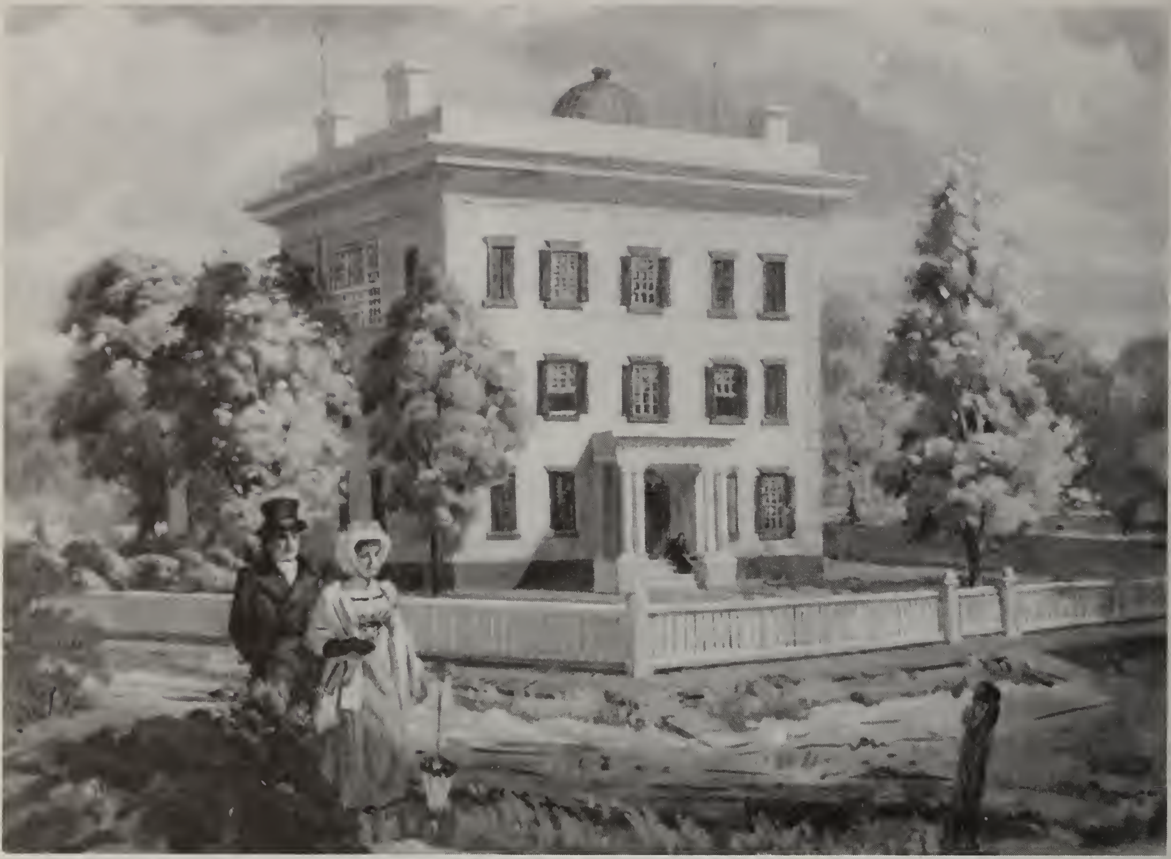
Gentlemen

I AM much obliged to you for the HONOUR you have confer'd on me, in making CHOICE of me, for your CHAIRMAN. I accept it with GRATITUDE, not that I judge myself equal to the task, but hope it will be a leading STEP to introduce some worthy GENTLEMAN, that will fill the CHAIR with more DIGNITY & HONOUR: The BUSINESS we are conven'd upon is a MATTER of great IMPORTANCE to MANKIND: though I must confess by the CONDUCT of the generality of MANKIND in this part of the WORLD it has been look'd upon as a MATTER of little or no IMPORTANCE. But however be that as it may we are all sensible that HEALTH is one of the greatest BLESSINGS that we can enjoy in this LIFE. The great CREATOR of our BODIES although form'd in such a wise & curious manner; has by his kind BENEDICTION indued many of the FACULTY with WISDOM & SAGACITY so as to remove the OBSTRUCTIONS which this curious FRAME is subject to, and to lengthen out LIFE & stop her in her CAREER to CORRUPTION. If this be so, what an entertaining & godlike STUDY is this? It is the greatest GOOD we can do to MANKIND not only so but we are viewing with pleasure the WISDOM of the MOST HIGH in forming such a CURIOUS MACHINE.

GENTLEMEN you that have been in PRACTICE longer or shorter find it, I make no doubt, an arduous UNDERTAKING, fatigued & exposed to a thousand CASUALTIES by DAY & NIGHT, different from the rest of MANKIND: Our MINDS in perpetual anxiety when our PATIENTS appear to be in DANGER. A PRACTITIONER should be of a firm CONSTITUTION, steadiness of TEMPER, sound in JUDGEMENT, free of access, COURTEOUS & COMPLAISANT in his DEPARTMENT, & kind to the POOR, critical in observing the SYMPTOMS of the several DISEASES that he is call'd to remove, & to make minutes of them for his future PERUSAL. Although we are form'd very much alike as to the anatomical part of our BODIES yet we are are very different as to TEMPER & DISPOSITIONS of MIND. The SOUL & BODY being united in such a manner that one is seldom affected without the other; some are of such a delicate make that the least indisposition will cause a fever, such patients should be treated in a soft & gentle manner, quite different from the hardy Soldier or Sailor, who fear neither GOD, man, nor DISEASES, we should be carefull not pronounce the disease incurable, before the PATIENT, of the delicate make, without mature deliberation, for in general those that are sick are very attentive to every WORD spoken by the PHYSICIAN and will swallow them as an hungry FISH will the bate. It is also necessary that every PRACTITIONER should be punctual in his engagements to the PATIENT, for he puts his LIFE in his hand under GOD, if he is not FAITHFULL it damps the PATIENT'S SPIRITS, & increases the DISEASE: not only that, but puts the PRACTITIONER out of repute. Is it not for the PUBLIC GOOD that every practitioner should be generously rewarded for his ATTENDANCE that he may visit his PATIENTS with CHEARFULNESS & punctuality and pay the demand of his APOTHECARY.

I HOPE GENTLEMEN you will pardon me that I should prescribe for your future CONDUCT in LIFE. May the BLESSINGS of HEAVEN ever attend this SOCIETY, that PEACE, BROTHERLY LOVE, and KNOWLEDGE in the ART of HEALING may florish, so as to exceed any of the renown'd SOCIETIES of the same DENOMINATIONS in Europe.

Leverett Hubbard's inaugural address is taken from the Minute Book of the New Haven County Medical Association and is published by the Association on the occasion of its bicentennial 1984. The original is deposited in the Yale University Archives.



THE MEDICAL INSTITUTION OF YALE COLLEGE

Artist—DEANE KELLER *Presented by Dr. George M. Smith*

At a meeting of the Connecticut Medical Society held in New Haven on October 16, 1799, a committee was appointed "to take into consideration and digest some regular system of education to be pursued by candidates for the practice of physic and surgery in this state." This committee reported in May, 1800, and set forth the program for the education of physicians. For six years, there was little attempt to realize the objectives of this report, but the idea was continuously before the members of the Society and the authorities of Yale College. President Dwight was deeply interested in it and Benjamin Silliman was appointed professor of chemistry and natural history in the College in 1802. Finally, through the initiative of the Reverend Nathan Strong of Hartford, a member of the Yale Corporation, a committee was appointed to inquire into the possibilities of establishing medical professorships. This committee addressed a communication to the State Medical Society suggesting a conference between the College and the Society concerning the establishment of a medical institution, and the Society considered the proposal at a meeting on May 20, 1807. In May, 1808, a report of this joint committee was distributed to the eight county medical associations, but it was not until September, 1810, that definitive action was taken and the school was incorporated under an Act which empowered "the President and Fellows of the Medical Society to join with the President and Fellows of Yale in the formation of the medical institution of Yale College." The institution was to consist of four professorships appointed by the Corporation of Yale after nomination by a joint committee from the Medical Scoiety and the Corporation.

During the year 1811-1812, the four professorships were filled by Nathan Smith in surgery and obstetrics; Eneas Munson in materia medica and biology; Benjamin Silliman in chemistry; and Jonathan Knight in anatomy and physiology. Eli Ives was appointed adjunct professor of materia medica and biology. In the fall of 1811, 37 students constituted the first class and instruction was started in a building James Hillhouse had erected as a hotel at the head of College Street. This building was subsequently purchased by the College for $12,500, part of a grant of $20,000 made to the School by the Connecticut Legislature. Later the School removed to the familiar old building on York Street, and the first building was remodeled and became known as South Sheff. It was demolished in the early 1930's to make way for Strathcona Hall.

"A Matter of Great Importance to Mankind": The Origins of the New Haven County Medical Association

SHERWIN B. NULAND, M.D., GUEST EDITOR

The little announcement was easily missed. Its few sentences of small print were tucked away down in the lower right hand corner of one of the oversized pages of the *Connecticut Journal,* among a few other items of limited interest. In the advertising space directly above it was a merchant's statement concerning flax-seed delivery, while the box below was occupied by a farmer's notice about a stray bull that had invaded his pasture. Those few lines between, signed by five of the most prominent members of the medical community of New Haven County, requested that all physicians and surgeons of the area meet with them at the Coffee-House on the city Green on Monday, January 5, 1784, "in order to consult and form Regulations, within the Line of their Profession of the utmost importance to the Public and themselves." The signatories were Drs. Leverett Hubbard, Aeneas Munson, Samuel Nisbit (a mis-print for Nesbitt), Levi Ives, and Samuel Darling. Their intention was to form a Society.

In spite of the fact that the organizers found themselves, as doctors so often do, between the seed and the bull, their notice attracted enough attention to draw a sizable group of their colleagues to the meeting. A chairman was elected, and the process of drawing up a set of rules was begun. As might be expected, the chairman was one of the founding five, Dr. Hubbard. His inaugural address, presented at a subsequent meeting on February 2, 1784 and reprinted in this bicentennial issue of *Connecticut Medicine,* was an admonition to bear always in mind the highest aspirations of the profession. In addition, he pointed out the fact of "the soul and body being united in such a manner that one is seldom affected without the other," which was another way of stating the ancient Greek teaching that disease occurs not in organs but in people.

On those infrequent occasions when modern physicians have the opportunity to read the ceremonial utterances of several centuries ago, we always seem to find in them some exquisitely lofty ideals and surprising timeliness for our own era. "Ah," we are apt to tell ourselves, "If only we could return to those glorious visions of yesteryear, when doctors were considered to be paragons of ethical living, and enjoyed the worshipful respect of society."

While I have no wish to detract from the wisdom of Leverett Hubbard's words or to dull the burnished image which local historians have created of his career, that oration with which he started off the long and eventful life of the New Haven County Medical Association would be difficult to distinguish from any of the countless other such speeches given before similar audiences during the 18th and 19th centuries. Although his statements have enormous importance to us as basic guideline truths of our professional lives, they were greeted by those who heard them as just so many platitudes, much as they would be if the president of our Association were to utter them today. Nevertheless, truth and idealism are no less worthy virtues for being expressed in clichés. The concern that it is not considered fashionable these days to speak publically about the old values of Dr. Hubbard does not mean that the overwhelming majority of the physicians of 1984 do not live by them. The fact is that such principles guide the actions of the medical community today to a greater degree than they did two hundred years ago.

What about the worshipful respect of society? Somehow, modern physicians really do think that time has toppled us from some imagined marble pedestal which we graced in former days. That self-delusion is a kind of misplaced nostalgia for something that never was; it flatters itself by ignoring or not absorbing the brass-tacks reality that the medical profession has never before occupied the esteemed position which we have held in the last half century. The present slight dip in the

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public acclamation to which we have become accustomed should not blind us to a clear view backward at the professional status, or paucity of it, which our predecessors endured in previous eras.

In this journalistic tribute to the 200th anniversary of the founding of the New Haven County Medical Association are included two essays that re-create certain aspects of the conditions in which our physicians worked daily in 1784. Thomas Forbes, a distinguished senior historian of medicine, has provided us with a commentary on the medical texts of the period, so that we may appreciate what was available for the self-education of both doctors and laity. Thomas Farnham, a specialist in Connecticut history, describes the city of New Haven as it was when the five doctors called their meeting. What follows in these next paragraphs is a brief over-view of the practice of medicine itself at that time: not very scientific, not very honored, and certainly not very well-paying.

A particularly appropriate way to set the theme for a description of 1784 medicine is to quote a statement made a few years later by Samuel Darling. In 1788 the New Haven County Medical Association published the first volume of medical transactions produced in our young country, entitled *Case and Observations,* concerning which there has been a great deal of discussion during this bicentennial year. Darling wrote an introduction to that little publication, in which he referred to America as "an infant empire, where the seeds of science, though widely disseminated, are just beginning to germinate." He might just as well have been writing of the state of medical knowledge in any country of the world. Nothing is more illustrative of the contemporary situation than the fact that it had only been as recently as 1775 that Antoine Lavoisier overthrew the fanciful Phlogiston theory of combustion, and introduced the use of the word *oxygen.* In the realm of diagnosis, the stethoscope would not be invented for another thirty-five years; percussion had been introduced only to be ignored and to need rediscovery early in the next century; even the technique of palpation was rudimentary, so that only obvious physical findings could be identified, beyond what was visible to a barely trained eye; much was read into the characteristics of the pulse and the appearance of the urine which was misleading or erroneous; the art of history-taking was virtually undeveloped. In other words, clinical medicine had not yet been born.

Of course, even in those few cases in which the primitive diagnostic methods yielded some idea of the underlying pathology, there was little possibility of categorizing it into some disease grouping that would be helpful in choosing a course of therapy, since nosology was based on rather superficial criteria. Giovanni Morgagni had only recently (1761) published his great *de Sedibus,* so most of the medical world was not yet sufficiently aware of the relationship between clinical findings on the one hand and the pathological changes that cause them, on the other. As a result, much of diagnosis and etiology remained somewhat mystical in 1784, and many disease states were attributed to the slings and arrows of obscure forces which today we would find laughable.

Actually, it really made very little difference that specificity of diagnosis was so often inadequate, in view of the fact that specificity of therapy was usually lacking as well. The healers were apt to prescribe bleeding, sweating, puking, purging, or blistering for a wide variety of conditions, often in combinations. There was virtually no surgery, except for trauma and certain gangrenous or purulent states. There were a few drugs that accomplished specialized objectives, such as opium and quinine, but doses were uncertain, preparations were unstandardized, and polypharmacy was king.

Where had the new nation's physicians learned their skills, if we permit ourselves just enough hyperbole to use such a generous word? Only 100 of the 1200 doctors in the colonial army had medical degrees, and the only schools that had yet graduated any students were the ancesters of the present University of Pennsylvania and Columbia faculties. Most American physicians with doctorates had gotten them at Edinburgh; of our founding five, only Dr. Nesbitt is said to have had the Edinburgh M.D., and even that is questionable. Very likely he had become a physician by training as an apprentice as had his colleagues, inheriting the errors and prejudices of their masters, and knowing nothing of the barely germinating science to which Samuel Darling referred.

But Darling was, of course, quite correct. The seed was indeed beginning to germinate, and the old theoretical hocus-pocus was preparing itself to leave the scene. And so, there is some poetic justice in the tongue-in-cheek symbolism of our professional ancestors' meeting-notice being printed between the seed and the bull. To carry the barnyard metaphor to an equally earthy conclusion, perhaps the scientific seed needed just that kind of fertilizer to grow in a soil and climate in which orthodox medicine had not much more to offer than did the many quacks of the day. For it was certainly the physicians' dissatisfactions with the bum steers and the bull of the old theoretical medicine that made them embrace with such enthusiasm the promise of the seeds of the new science. Among the most avid embracers would be the doctors of New Haven County and the state of Connecticut.

Because few physicians were particularly well educated, because their methods depended so heavily on unfounded and unprovable theories, because there were no high standards that qualified a man to call himself Doctor, and because the healers were often so overtly in business competition with each other, the townspeople of New Haven and elsewhere did not look upon them as especially valued members of society. Although Dr. Hubbard spoke of how "different from the rest of mankind" was the medical profession, the laity did not necessarily view the difference as something to boast about. Two factors changed that image, a metamorphosis that would take more than a hundred years to be complete.

In fact, January 2, 1784, proved to be the date of birth of a stage in one of those factors, the organization of medical societies in the United States. By improving standards, by supporting high-quality medical education, by the establishment of rigid codes of ethics, and by encouraging the growth of scientific medicine, the medical societies of America were fundamental to the process by which this country became the world's center of the healing arts. As members of the second oldest continuing county society* in the United States, New Haven physicians have been in the vanguard of that evolution. When the American Medical Association was founded in 1843, it was a member of our society, Jonathan Knight, who was its first president.

The other factor in the rise of our profession has been the advent of scientific research and its application to patient care. In this arena also, New Haven physicians have played a significant role. Clinicians and researchers who have worked or trained in our medical community have been involved in some of the most important advances which American medicine has contributed to the world. But as worthy as those contributions have been, the Society's real source of greatest satisfaction lies elsewhere as we celebrate our 200th anniversary: we point with amply justified pride to the high standards of medical care that characterize the daily practice not only of the physicians of New Haven County, but of the entire state of Connecticut as well.

That which before us lies in daily life
Is the prime wisdom.

John Milton
Paradise Lost, Book VIII.

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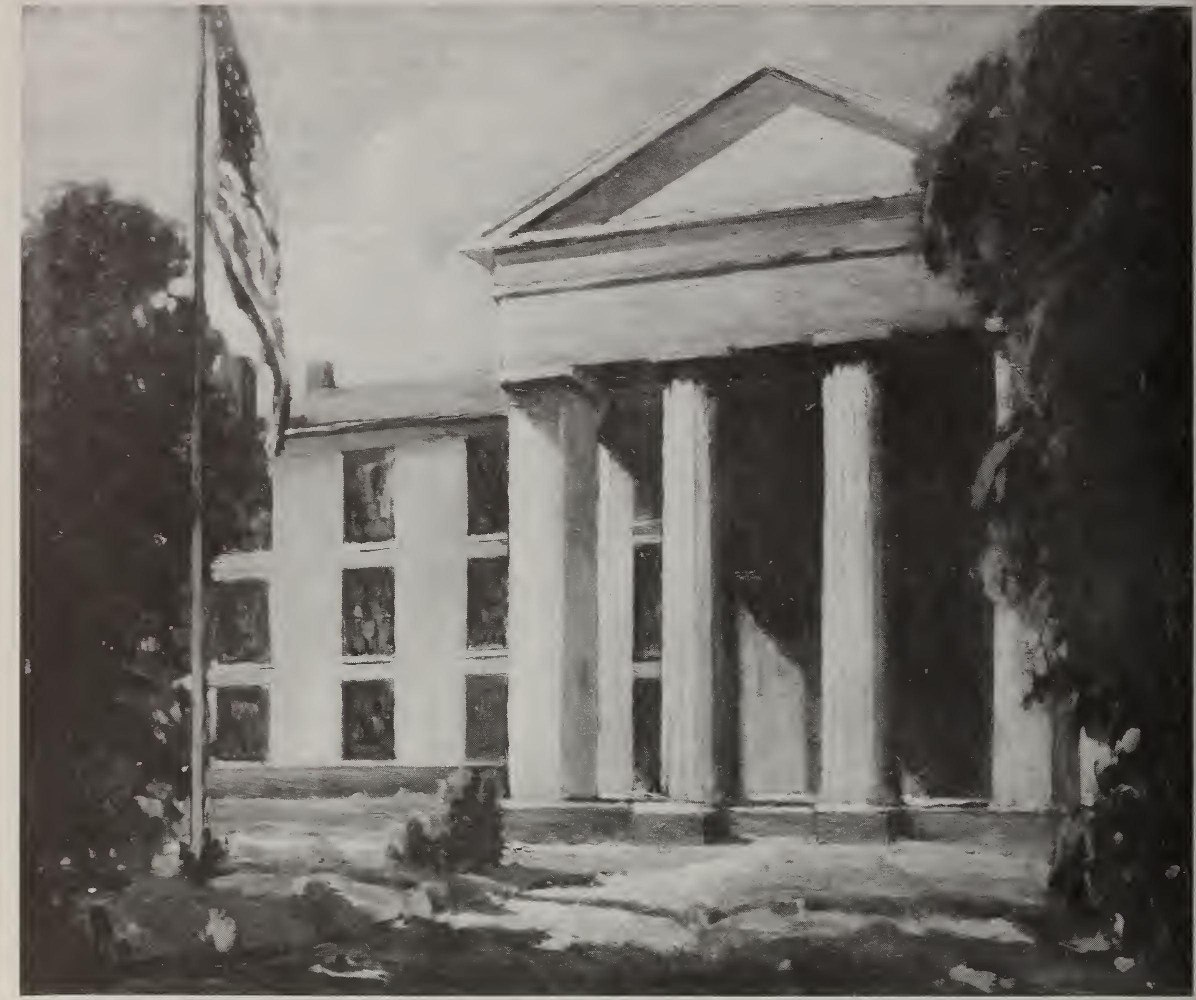
*This claim was made at the time of the Association's one-hundred-fiftieth anniversary in 1934. After looking for almost a decade, I have found no evidence to contradict it. Can you guess which county society is older?

Incidentally, at least one eminent authority, F.R. Packard, wrote that the New Haven County Medical Association is actually the *ninth* oldest in the United States. I would prefer to think that we are really the second. If continuous existence is the criterion, we are the *first!*

In the dedication of his *Holy War,* Thomas Fuller has some very happy and characteristic remarks on the bounden duty of a man to better his heritage of birth or fortune, and what the father found glass and made crystal, he urges the son to find crystal and make pearl. Your heritage has been most exceptional, and, I believe, from all that I know of the profession in this city and State, that could your fathers return they would say that of their crystal you had made pearl. One cannot read their history as told by Bronson, or as sketched by your distinguished citizen, my colleague, Dr. Welch, without a glow of admiration for their lofty ideals, their steadfastness and devotion, and for their faith in the profession which they loved. The times have changed, conditions of practice have altered and are altering rapidly, but when such a celebration takes us back to your origin in simpler days and ways, we find that the ideals which inspired them are ours to-day—ideals which are ever old, yet always fresh and new, and we can truly say in Kipling's words:

The men bulk big on the old trail, our own trail, the out trail,
They're God's own guides on the Long Trail, the trail that is always new.

—Comments of William Osler, to the physicians of New Haven, 1903, in a talk entitled "The Medical Society in the Education of Physicians."



THE GENERAL HOSPITAL OF CONNECTICUT
THE NEW HAVEN HOSPITAL

Artist—HAROLD SAXTON BURR *Purchased by the Society*

At a meeting of the State Medical Society in New Haven on May 10 and 11, 1826, it was "voted unanimously, that we approve of the decision to establish a general hospital in the City of New Haven and that Drs. Ives, Knight, and Hooker be a committee to procure pecuniary aid from the Legislature of the state and from such other sources as they may think best." The hospital was chartered by the Legislature on May 26, 1826, and a project to acquire funds was undertaken by the appointment of Dr. John Skinner as agent to solicit subscriptions. On December 18, 1829, it was voted that the buildings for the hospital be located "upon the hill on the southwestern side of the City of New Haven and northwest of the road leading from the foot of Church Street to West Haven" and that, the directors determine "the style and extent of the building to be erected thereon, provided the expense of said buildings shall not exceed the sum of $15,000." Dr. John Skinner was continued as agent at $2 a day and expenses.

In 1830, Ithiel Town, a celebrated architect, was retained to prepare plans for the building. Money was hard to come by, although the State of Connecticut had appropriated $5,000 in 1828, but finally, late in 1830, a contract was let for the erection of the building to Sidney M. Stone, Esq., "for less than $13,000."

This Greek temple was operated by the U.S. Army as the "Knight Hospital" during the Civil War and was known affectionately as "Old North" by many generations of house officers. It was demolished in 1930 to make way for the present hospital buildings.

New Haven, 1784

THOMAS J. FARNHAM, PH.D.

In 1784 the state of Connecticut established the city of New Haven. What did that city look like? How was it similar to the New Haven of today? How was it different? Travel back two hundred years and visit the fledgling city and in the process begin to see what New Haven has gained and lost during those two centuries.

Governor Jonathan Trumbull signed the city charter in January 1784. Created from the old town that Theophilus Eaton and John Davenport established 146 years earlier, the new city was smaller, both in terms of population and of area, than the town just prior to incorporation had been. In fact, the town in 1783, at the end of the Revolution, had been the sixth largest community in the United States, its population numbering nearly 8000 persons. It had then included what are today the separate towns of West Haven, Hamden, North Haven, East Haven, and parts of Woodbridge and Bethany and had spread out over an area of about 132 square miles. The city's new boundaries were more similar to those of today than to those of the old town: the Quinnipiac River on the east, the West River on the west, the Mill River meadows at the base of East Rock on the north, and the harbor on the south. The city was only ten per cent of the size of the old town.

The loss of population was also impressive although not so dramatic as the loss of area. The city's population after incorporation included only 3400 souls, less than half its former number. Within this population were few persons who were not Protestant—in particular, Congregationalist—and of English ancestry. Ethnic and religious diversity was nearly a century into the future for New Haven.

There were compensations for New Haven's losses of population and territory. In addition to enjoying the distinction of being one of only two cities in the state at the time (New London being the other), New Haven was now, as a municipality, better able to encourage trade than it had been. The city government had considerable control over the commerce that took place within its limits and now had the authority to improve its roads and harbor without the General Assembly's approval. The charter further created a Mayor's Court which enjoyed jurisdiction over civil cases arising in the city, thus expediting settlements in such situations. And the newly established position of mayor provided more administrative direction than New Haven had known since its earliest years. Contemporary comments indicate that New Haveners were overjoyed with their new status.

New Haven, despite its new designation, still possessed a distinctly rural flavor. Its harbor was inferior to New London's. The Long Wharf then extended fewer than 2000 feet into the harbor. Large ships had to deposit their cargoes at the pier, an eighty-foot square, manmade island in the channel. Moving goods by smaller craft from the pier to the Long Wharf was time consuming, expensive, and a serious deterrent to the growth of maritime New Haven. In 1784 only thirty-six visiting vessels, most engaged in the coastal trade, called at New Haven while merely thirty-three locally-owned vessels sailed from New Haven, again primarily for coastal ports. *The Connecticut Journal,* the local newspaper, included far more notices of lost, strayed, or stolen livestock than of exotic goods from distant ports. Barter remained the medium of exchange. Merchants were happy to receive "country produce" in exchange for rum, sugar, or other imported goods. Transactions between neighbors almost always took the form of barter: firewood for cider; salted meat for dried corn; the possible combinations were endless.

Most of the residents of New Haven lived around the old town plot, the nine contiguous squares surrounded by what are today known as State, Grove, York, and George streets,[1] or in the area that ran from the town plot to the waterfront. The remaining areas of the city were sparsely populated. If one traveled beyond Grove Street on State, he would encounter only farmers' fields. Likewise, a sojourn west on Elm would bring one into a similarly pastoral setting once he passed beyond York Street. The old Puritan idea of living in compact settlements was still a part of eighteenth century New Haven's thinking.

THOMAS J. FARNHAM, PH.D., Department of History, Southern Connecticut State University, New Haven, CT.

Ezra Stiles, who in 1784 was the president of Yale College, had a penchant for statistics, a penchant for which students of New Haven history have long been grateful. He estimated that there were about 400 houses in the city. Most were center-chimney, wood-frame, clapboard structures such as twentieth century persons associate with colonial Connecticut. To stand on the Green today and look north to the Graduates Club and the Faculty Club on Elm Street is to obtain a fairly accurate picture of how the substantial dwellings of Stiles's era appeared.

By 1784 some of New Haven's most impressive houses dignified the recently developed area near the harbor. The commercial firm of Samuel Broome and Jeremiah Platt moved from New York City to New Haven in 1784 and occupied a stately residence on what modern New Haven knows as Wooster Street, the harbor then coming within a block of that street. Near the Broome and Platt house was one of New Haven's most distinguished homes, the former residence of David Wooster, New Haven's Revolutionary War hero who had been killed in 1777. On Water Street, the south side of which ran along the harbor, Benedict Arnold had built before the Revolution an elegant house next door to the brick-ended house of his father-in-law, Sheriff Samuel Mansfield. Until James Hillhouse undertook to develop the area north of the Green, probably no more fashionable neighborhood existed in New Haven than the area around Water and Wooster streets.

The city's public buildings were all located in the vicinity of the Green. The buildings of Yale College stood just west of the Green on a street soon to be named College. Three brick buildings, all of Georgian architecture, provided a suitably dignified setting for the college which then included 225 students. Until 1782 Yale's appearance had been less than a source of pride, for until that date a monumentally ugly, wooden structure, 170 feet long and three stories high, had dominated the campus. Built in 1718 and known as "Old College" or "Yale College House," it had fortunately been demonished in 1782, and a new brick dining hall had by 1784 taken its place. The other Yale buildings were South Middle, later to be called Connecticut Hall and even then the oldest building on the campus, and the Chapel or Athenaeum. President Stiles lived just across Chapel Street from these buildings in a fine wooden house owned by the college.

On the southeast corner of Chapel and College—now the location of the Taft Apartments—Isaac Beers operated a combination bookstore and tavern; in this popular gathering place much of New Haven's business, public and private, took place. Isaac's brother, Elias, owned a store farther south on College. The store was also a meeting place because Elias was, in addition to being a merchant, New Haven's postmaster. He and Jonathan Fitch, the collector of customs, were the only Federal officials whose presence was felt by provincial New Haven. Twice a week Elias Beers sent the mail off to New York and once a week to Boston and to Hartford.

On the Green itself were several buildings. The "new brick meetinghouse," built in 1757, ran parallel to the one-block long, recently cut road that would eventually be called Temple Street. The brick meetinghouse was the third such structure built at this location. In 1814 the present Center Church would replace it. On three of its sides the brick meetinghouse was surrounded by the ancient town burying ground. The burial ground, like the Green itself, was entirely unenclosed, steeply pitched from west to east, without trees, often used to graze cattle, and generally unkempt. It contained graves that dated back to the days of Eaton and Davenport. Between the brick meetinghouse and what became Chapel Street was the State House,[2] an imposing brick building contructed in 1763 to replace the old 1718 State House that stood in disrepair on the western edge of the Green. The old State House was used in 1784 by the Hopkins Grammar School. It and an even more dilapidated jail standing next to it provided a disreputable backdrop for the handsome brick meetinghouse and the 1763 State House. By the end of 1784, the jail was gone, demolished on orders from the city. Neither adding nor detracting in any serious way from the aesthetic quality of the Green was the white meetinghouse of the Fairhaven Society. Built in 1770, it faced south on Temple Street. It would be replaced in 1815 by the present United Church.

The lower Green was a market area. In fact in 1784, the city erected a "market house" on the southeast corner of the Green with the hope that most of the city's trading would take place in that location where the city's inspectors of Indian corn, rye, and flour and its packers of beef, pork, and fish could keep a close watch on product quality. But New Haveners were too independent to accept the idea of a central market or to tolerate such bureaucratic interference.

Trinity Episcopal Church was located on the thoroughfare today known as Church Street. Located at what was then called Cutler's Corner, the southeast corner of Church and Chapel, this building was the only church—as opposed to meetinghouse—in New Haven and so provided the reason for the street's eventual name. Trinity remained at Cutler's Corner until 1814 when it moved to its present location at Chapel and Temple. In 1748 the White Haven Society had constructed the blue meetinghouse at Church and Elm. It was still very much in use in 1784 and would continue to be until the White Haven Society and the Fairhaven Society merged to form the United Society and build the United Church.

While there was an abundance of shops in New Haven in 1784, most of them were adjuncts to private homes. Practically all New Haveners worked at home. Professional men merely designated rooms in their homes as offices. Merchants often did the same or built small commercial additions to their homes. If an economic activity might detract from the serenity of home life, an outbuilding could easily become a shop. Stores and factories and office buildings as we know them did not exist in 1784 in New Haven. Neither did libraries, banks, hospitals, named streets, paved roads, or sidewalks exist. On the other hand, the city endured an abundance of mud in winter and spring and dust in summer and autumn. Outhouses and wells, frequently residing in unhealthy proximity, were also the order of the day.

The difficulties of travel kept most people at home most of the time. The roads that connected New Haven with the outside world remained in essentially the same primitive condition in which they had been a century before. Not until the turnpike era that came after 1790 would any substantial improvements appear. For the hardy there were two stage coaches a week to Hartford, one on Wednesday and one on Saturday. Every Monday morning the Boston stage departed New Haven; by taking the most direct route and by frequently changing horses, it would, with a bit of luck, make Boston by Thursday evening. The most convenient means of travel was by water. Weekly packet ships offered reasonably comfortable transportation to New York or to New London and then Boston. But such far off places were known to most New Haveners only through stories brought back by their more cosmopolitan neighbors.

As much of a small town as New Haven was in 1784, it was not without its share of educated, even erudite, citizens. Roger Sherman, the city's first mayor, participated in virtually every aspect of the founding of the United States, from the signing of the Declaration of Independence to the drafting of the Constitution. He and James Hillhouse, Jonathan Ingersoll, and Pierpont Edwards were among the city's most prominent attorneys. Leverett Hubbard, Eneas Munson, Samuel Nesbitt, Levi Ives, and John Spalding were all respected physicians. Hubbard served during 1784 as the first president of the New Haven County Medical Society.

But no resident of New Haven rivaled Ezra Stiles for breadth of knowledge and openness to new ideas. Born in North Haven, educated at Yale, for twenty years a minister in Rhode Island, Stiles returned to New Haven in 1778 to become president of Yale. "He was truly a learned and pious man inclining to enthusiasm on the cause of civil and ecclesiatical liberty, and a polished gentleman of the old school," wrote David Daggett, the city's sixth mayor. Stiles, 56 in 1784, was a member of the American Philosophical Society, a Doctor of Divinity from Edinburgh, and certainly one of New Haven's most civic minded citizens. It was he along with James Hillhouse who designed the city seal.[3]

Stiles also made an effort to see that important visitors left the new city with a positive picture of the municipality. In 1785 he accompanied Robert Hunter, Jr., a London merchant, to the bell tower of the Yale Chapel, "from the summit of which," Hunter later wrote, "you have a commanding view of the whole city: the harbor, the shipping, the sound, Long Island, Newhaven River [the Quinnipiac], the West River, and the beautiful cultivated country round—the elegant mountains forming a striking contrast with the delightful valleys." Altogether Hunter concluded that New Haven was as beautiful as any town he had seen; "it looks," he said, "like a paradise."[4]

Whether twentieth century visitors would regard the New Haven of 1784 as a paradise is questionable. The present generation may well find the city of two hundred years ago to be frustratingly inconvenient and unsufferably provincial. To be caught in a city of only 3400 persons, one without a library or a symphony, much less indoor plumbing, might not appeal to many modern Americans. But, on the other hand, to live in a land where the rivers and the harbor were unsullied, where the landscape was largely unadulterated, where the air was breathable, and where men as talented as Roger Sherman and Ezra Stiles were devoted to the welfare of the city might be tempting even to some modern persons. Fortunately the choice between then and now is one no person will ever have to make. Because the city of 1784, for better or worse, is part of New Haven's irretrievable yet potent past.[5]

REFERENCES

1. New Haven's streets were not officially named until the autumn of 1784.
2. During the eighteenth century and most of the nineteenth century, New Haven was, with Hartford, co-capital of Connecticut.
3. Thomas J Farnham, "David Daggett's 'New Haven Sixty Years Ago and Since,' " Journal of the New Haven Colony Historical Society (December 1969), XVIII, 96.
4. Louis B Wright and Marion Tinling, Quebec to Carolina in 1785-1786: Being the Travel Diary and Observations of Robert Hunter, Jr (San Marino, California, 1943), p 156.
5. Useful discussions of New Haven in 1784 may be found in Rollin G. Osterweis, Three Centuries of New Haven (New Haven, 1953), pp 157-175; Franklin B Dexter, "New Haven in 1784," Papers of the New Haven Colony Historical Society (1888) IV, 77-138.

Books and Broadsides: What Colonial Physicians Read

THOMAS R. FORBES, PH.D.

ABSTRACT—The two hundred medical imprints published in Colonial America before 1785 are analyzed as to format, place of publication, author, and content. Principal topics of interest to Colonial medical practitioners are discussed, in particular the inoculation controversy.

American Colonial physicians were variously trained. Some had studied in European medical schools, some had been indentured as apprentices in America, and some probably opened a practice on the strength of their reading and observation alone. The Colonies would not offer formal medical education until 1765, when the Medical School of the College of Philadelphia would open its doors, although private instruction in midwifery and anatomy had begun a few years earlier.[1] Any conscientious practitioner would welcome professional books and pamphlets.

Well trained Colonial physicians were acquainted with at least some of the writings of the great European authorities—Boerhaave, van Swieten, Sydenham, Cheselden, Smellie, and others; their works had been published in Europe. But what medical books and pamphlets were coming off the presses in the colonies? To answer this question one can turn to Robert B. Austin's *Early American Medical Imprints, 1668-1820*[2] *(1961).* An alternative source is Francisco Guerra's *American Medical Bibliography 1639-1783.*[3] Austin's bibliography has supplied the data for the present analysis and interpretation. It is a pleasure to express my indebtedness to his compilation.

A few items listed by Austin have been omitted from my study because they are duplicates except in minor detail. There remain two hundred books, theses, broadsides, and pamphlets printed before 1785. Just over three-quarters of these were less than fifty pages in length. Seventy-five items came from presses in Philadelphia, thirteen being from the printing establishment of Benjamin Franklin. Boston with sixty-eight imprints ranked second, New York City with fifteen was third, and Williamsburg with six was fourth. The remainder were from other towns in the coastal states. Connecticut's total was three imprints each from Hartford and New London, two for New Haven, and one each from Lebanon and Norwalk.

The printing of medical and other books might have begun earlier had it not been for royal restriction. Charles II permitted only one printing press in Massachusetts until 1674, although the press had been established in Cambridge in 1639.[4] Boston had a bookseller's shop by 1670 and several more were in business by 1686. Their volumes were mostly printed in Europe. At least one of the shops handled medical texts.[5]

By 1785 no journals had yet appeared in the Colonies. The first American medical journal seems to have been the *Medical Papers,* published by the Massachusetts Medical Society beginning in 1790,[6] although Wigglesworth indicates that the *Boston NewsLetter,* printed weekly beginning in 1704, occasionally carried accounts of surgical operations and other medical information.[7]

With a few exceptions, all of the two hundred American Colonial imprints up to 1784 were in English. Four theses in Latin for the College of Philadelphia, dealt with dropsy, fevers, intermittent fever, and inoculation. Also in Latin were three pharmacopeias and a New York printing of an abridgement of William Cullen's *Synopsis nosologiae methodicae.* Cullen (1712-1790), a distinguished Scottish physician, was renowned for his *First Lines of the Practice of Physic,* originally produced for the students at the University of Edinburgh. In addition to its European editions, there were no less than nine printings of this book in America between 1781 and 1816, testimony to the importance of some British medical works to Colonial physicians. Of the six American imprints in German, three were on veterinary medicine and one, published for the layman, appears to have been a translation of *Every Man His Own Doctor,* written anonymously by John Tennent, a

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Virginia practitioner. There were two broadsides, large single printed sheets, in German. One extolled an essence of bitters and the other was a *Notice to Those Desiring Beneficial Doctors.*

No less than forty-six imprints related to smallpox and the inoculation controversy. Inoculation was introduced into America during a smallpox epidemic in the Colonies in 1721. Cotton Mather (1663-1728), the distinguished New England clergyman and medical theorist, had been educated in both theology and medicine. Although very active as a Congregational minister, he still found time to follow scientific experimentation and to write extensively. Mather, who was the first American to be elected a Fellow of the Royal Society,[8] discovered in the Society's *Philosophical Transactions* an account of variolation as practiced in Turkey. However, even in the face of the smallpox epidemic that was then raging, the New England divine was unable to persuade several Boston physicians to try the new procedure. Finally his friend Dr. Zabdiel Boylston undertook to inoculate the latter's young son and two black servants and was successful. But much dissension developed over both the value of, and the best technique for, variolation.[9] The religious element in the controversy is reflected in the title of a broadside by Increase Mather (1629-1723), father of Cotton Mather, *Several Reasons Proving That Inoculating or Transplanting the Small Pox, Is a Lawful Practice, and That It Has Been Blessed by God for the Saving of Many a Life* (1721). Rhode Island, Connecticut, and Massachusetts issued broadsides announcing laws for the control of the disease. Arguments for and against inoculation continued for years to appear in print.

Works on the general practice of medicine and medical education were relatively scanty. They included the two books by William Cullen already mentioned and a Philadelphia printing in 1784 of the tenth edition of Sir John Elliott's *The Medical Pocket-Book; for Those Who Are, and for All Who Wish to Be, Physicians.* Elliott (1736-1786), a Scot, evidently possessed varied talents. While still a young man he served as ship's surgeon on a privateer. With funds accumulated from this dubious enterprise he attended St. Andrews University and was awarded his M.D. in 1759. Elliott developed a highly successful practice and became physician to the Prince of Wales in 1778.

Another notable volume was Dr. John Morgan's plea in 1765 for the reform of medical education, *A Discourse Upon the Institution of Medical Schools in America.* Morgan also produced a book recommending inoculation. His remaining publications related to his unjust dismissal by Congress in 1777 from his post as Director General and Physician in Chief of the American Army and his replacement by William Shippen.[10]

If there was a scarcity of American imprints on general medicine at the professional level, there were plenty of popular medical books for the layman. (Did medical practitioners also read these?) Medical information obtained short of direct professional consultation has been popular for centuries, never more so than today. In Colonial times local scarcities of physicians must have given such literature an additional appeal. At least nine medical volumes for laymen, some in more than one edition, came off the presses between 1745 and 1772. Among them were Benjamin Rush's *Sermons to Gentlemen upon Temperance and Exercies* (1772), John Armstrong's poem, *The Art of Preserving Health,* and *Primitive Physick: or, An Easy and Natural Method of Curing Most Diseases,* 1764 and 1770 Philadelphia reprints of an earlier handbook by John Wesley, English evangelist and leader of Methodism but not a medical man. Highly successful was the pseudonymous *Aristotle's Compleat Master Piece . . . Displaying the Secrets of Nature in the Generation of Man . . . to Which Is Added, A Treasure of Health.* This extraordinary manual for laymen achieved not only numerous London editions but twenty-one American printings by 1814. Even more popular was *Domestic Medicine,* or the *Family Physician,* by William Buchan, M.D. It had five separate printings in Philadelphia and one in Norwich, Connecticut, between 1765 and 1784. But these were only a paltry part of the total. According to Rosenberg,[11] no less than one hundred forty-two separate editions of this work had appeared on both sides of the Atlantic by the latter part of the nineteenth century. A manual of self treatment, it depended largely on herbal remedies. Outright quackery is suggested by such titles as that of an anonymous 1731 reprint of the London edition of *An Abstract of the Patent Granted by His Majesty King George to Benj. Okell, the Inventor of a Medicine, Call'd Dr. Bateman's Pectoral Drops,* Robert Bass's *Doctor Keyser's Famous Pills, Imported and Warranted Genuine* (1763), and Hugh Martin's *A Narrative, of a Discovery of a Sovereign Specific, for the Cure of Cancers* (1782, 1784).

Colonial therapy depended heavily on botanicals and other drugs. Practitioners, who had to know a good deal of medical botany, must have welcomed such volumes as Thomas Short's *Medicina Britannica: or A Treatise on Such Physical Plants, as Are Generally to Be Found in Great Britain* (1751) and William Brown's *Pharmacopoeia simpliciorum & efficaciorum.* Austin's bibliographic note tells us that "Brown was stationed at the army hospital at Lititz, Pa., and was physician-general of the Middle Department of the Continental Army" (1961, p. 33). Several druggists published lists of their wares, for example, John Tweedy's *A Catalogue of Druggs* [sic] *and of Chymical and Galenical Medicines* (1760).

Medical imprints of the period also included a scattering of works on specific diseases, among them measles, gout, West India dry gripes, throat distemper (usually diphtheria), pleurisy, fevers, putrid sore throat (typhus), and consumption. Nine printings of Daniel Defoe's popular and perhaps partly fictitious accounts of London's great epidemic of plague in 1665 were produced in America between 1763 and 1806.

Only one work on pediatrics had appeared in America by 1784, William Cadogan's *An Essay upon Nursing and the Management of Children* (1772, 1773). There was also only one volume on geriatrics, John Hill's *The Old Man's Guide to Health and Longer Life,* a Philadelphia reprint in 1775 of the London version. The tenth edition of another English volume, *Onania . . . and All Its Frightful Consequences,* was reprinted in Boston in 1724. Five different works extolled hydrotherapy and the virtues of tar water; the great Benjamin Rush wrote of his *Experiments and Observations on the Mineral Waters of Philadelphia, Abington, and Bristol, in the Province of Pennsylvania* (1773).

Still other books and numerous broadsides dealt with military medicine, hospitals, and the quarantine of ships during a smallpox epidemic. Most of these publications, not surprisingly, were engendered by the American Revolution. Curiously enough, only one book was concerned with the practice of surgery, John Jones's *Plain Concise Practical Remarks on the Treatment of Wounds and Fractures; to Which Is Added a Short Appendix on Camp and Military Hospitals; Principally Designed for the Use of Young Military Surgeons in North-America.* The date, 1775, and the title tell it all. The book was reprinted twice in the following year.

Significantly, there was also only one volume on midwifery, John Oliver's *A Present to Be Given to Teeming Women, by Their Husbands, or Friends* (1694). Labor was mostly managed by midwives. Evidently neither they nor the medical practitioners were thought to constitute much of a market for books on childbirth. At least five books on the subject, written for women, were extant in England by the end of the seventeenth century even though, in the opinion of Thoms, these volumes were of inferior quality. The first public course of instruction in midwifery, that of by Dr. William Shippen of Philadelphia, was not instituted until 1762.[12]

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Worthington Hooker (1806-1867): Physician and Educator

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Worthington Hooker played an unusually creative role in the medical profession and American society in the mid-19th century. He was both conservative in that he was a devoutly religious man who opposed Darwin's doubts about the unique status of humans in the animal kingdom, and a progressive reformer in education who sought to revolutionize the teaching of science in schools and colleges. Unlike some religious writers, he did not oppose aggressive scientific research because of any fear of undermining public faith, but sought to evangelize teachers, citizens and school children about the excitement and cultural importance of nature closely studied and enthusiastically presented. To Hooker, the natural world revealed the wisdom of God.

As Professor at the Yale Medical School and a practicing physician, Hooker not only stoutly defended contemporary "regular" medicine against the winds of fads, delusions of quackery and rival theories such as that of homopathy but also promoted a clear understanding of medical ethics which implied obligations upon patient, as well as upon physician. Hooker's *Physician and Patient* (1849) has been described in the recent *Encyclopedia of Bioethics* as "the only comprehensive view of professional ethics published in book form by a North American practitioner before 1900."[1]

He was a cheerful man who went about daily doing good in the practical and local ways which endeared him to the communities in which he worked. Still, he found time, somehow, continually to digest writings of others and to write a lengthy series of lectures, textbooks, and magazine articles for adults and children, the latter occasionally under the pseudonym "Uncle Worthy."

Hooker was born in Springfield, Massachusetts on March 3rd, 1806 (a day later than the date inscribed on his tomb in New Haven's Grove Street Cemetery), the son of Judge John Hooker and Sarah Dwight. After graduating from Yale College in 1825, he pursued medicine and took his MD at Harvard Medical School in 1829. Settling in Norwich, he took an active role in community life and married Mary Ingersoll in 1830.[2] Hooker began practice when commonly accepted patterns of treatment were dissolving into confusion. He eventually saw himself living in medicine's "transition state" when a chaos of medical theories and nostrums would, he hoped, gradually evolve into a medical profession solidly based in science and respected by the public. The question he repeatedly asked himself and his readers was, What is the best course to follow in this tumultuous period?

The Physician

Fifteen years into his Norwich practice, he read an essay to the Connecticut State Medical Society on "The Respect Due to the Medical Profession and the Reasons It Is Not Awarded by the Community."[3] Hooker bemoaned confusion over the physician's status. How could the well-educated and responsible physician be detected and valued in the swirl of conflicting claims and the deluge of quack nostrums? With great difficulty, it appeared. In retrospect, we know that although we can fully sympathize with Hooker's faith in the educated physician, we must remind ourselves that there was very little from which to choose among the competing theories with regard to efficacious treatment. This is exemplified by Hooker's own support of calomel against its detractors. The Connecticut State Legislature also found choice difficult and in 1842 repealed the State licensing law.[4] Dr. Hooker's advice for relieving the lamentable situation of medical men in 1844 was that they should, first, eschew all involvement with nostrums, radical theories such as Thompsonism, and unjust competition with fellow members of the profession. He pleaded for the camaraderie of physicians acting "in unison for the good of the profession as a whole."[5] By so acting, the profession would be able to survive what Hooker called "the crisis coming now." He warned that "Never have the opinions of the people been so thoroughly unsettled in regard to different remedies and modes of practice;

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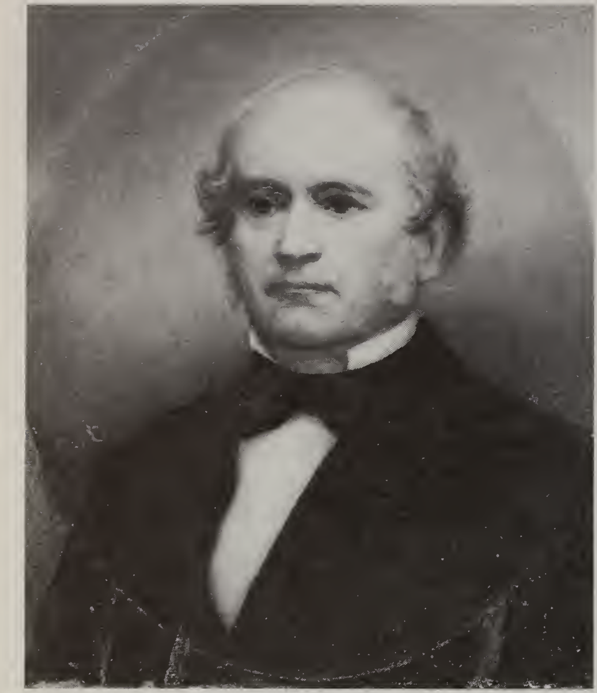

Figure 1
Worthington Hooker, M.D., 1806-1867. (by L. Kellogg) *Courtesy of the Yale Art Gallery.*

and the remark is heard every day, even from men of intelligence, 'In medicine I know not what to believe.' "[6]

Understandably, Hooker welcomed the stirrings among physicians which led to the formation of the American Medical Association in 1847. This promised a practical organization which could unite physicians in the way he felt was necessary to combat popular doubts and variegated health service deliverers. The ideology which united the profession—or ought to unite the profession—was located in the Code of Medical Ethics adopted at the convention held in Philadelphia in 1847. This Code absorbed much of Hooker's interests and thoughts. When two years later he published his major work, *Physician and Patient,* he developed in greater detail the themes found in the Code and the background of the profession which he had sketched in his address before the State Society in 1844.[7] *Physician and Patient* provided an analysis of the patient-physician relationship which was influential in the 19th century; its continuing importance is reflected by a reprinting as recently as 1972.[8]

Hooker began by stressing the "uncertainty of medicine." He contrasted medicine with chemistry in which the results were usually definite. In medicine, organs in different parts of the body might respond to the same disease by a kind of "sympathy." Symptoms might be produced far from the actual seat of the disease, as with right shoulder pain in liver disease. Sadly, many causes of disease were unknown, and a combination of causes, acting long before the physician was consulted, complicated diagnosis. Even nature itself causes problems as it attempts to resist the onslaught of disease. Thus, vomiting may not be a sign of disease, but rather nature's way of emptying the stomach.

Hooker emphasized mental influence on disease, to an extent, I believe, that would warm the heart of Norman Cousins. The effect of the mind on disease, he argued, "is constant in all diseases; sometimes plain to be seen . . . often entirely concealed from the most careful scrutiny; and sometimes revealing itself slightly, so that the watchful eye of the physician catches mere glimpses of it, like passing shadows gone in a moment . . . . The cordial which is administered is often in part or wholly neutralized by mental depression, while it is essentially aided in its effects by the genial and animating influence of hope."[9] Finally, uncertainty in medicine is due to individual idiosyncrasies which affect the response to medicine. Persons may over-react to simple substances such as roses or strawberries, or react atypically to opium or ipecac. Hooker compares this kind of physiological uncertainty again to a chemical reaction should the vessel in which the chemicals were mixed contribute in some unknown way to the final product.

Skill in medicine consists in taking into account the unavoidable uncertainty of the profession while "appreciating the condition of the patient in all respects, and applying remedies in the best manner to relieve this condition."[10] Although this recommendation may seem bland, Hooker was warning physicians away from viewing a patient from one special aspect. There are those who have a tendency, he wrote, to "get a sort of attachment to some localities in the system, and are disposed always to look to their favorite quarters in their search after the seats of disease."[11] Similarly, certain modes of investigation may be excessively favored by a physician. It is sobering to realize that these admonitions, so similar to contemporary exhortations, were made almost 150 years ago. Preeminently, above diagnosis and application of remedies and the observation of the patient, Hooker placed the instillation of hope. The physician should "cheer his patient with his hopeful voice and manner, amid all the gloom and peril of the journey of sickness; and should hold out to him, in all the seasons of despondency, so far as truth will allow him to do so, the hope that he will at length reach the end of that journey in safety."[12]

After realistically—and probably to the reader of his day not too optimistically—describing the practice of the educated physician, Hooker turned to the popular errors of quackery, the rival theories of medicine, Thompsonism, homeopathy and "natural bone-setters." He was convinced that a major source of popular error resided in the common belief that cure of disease requires the application of medicines. Hooker was a strong believer in *vis medicatrix naturae*—the curative power of nature. That every ailment required treatment was to him a dangerous notion. He further admonished physicians and patients not to attribute effect to treatment just preceding the cure, *post hoc propter hoc,* or look for a single treatment to cure all diseases, or succumb to the faith that all disease is of one kind.

His attack on the advertising of patent nostrums promising extravagant cures would be echoed near the turn of the century in the battle to secure the Pure Food and Drug Act. He inveighed against the secrecy of the nostrums' ingredients, the extravagant cost of advertising and the phony testimonials displayed by the nostrum manufacturers. He found a little solace in the rapidity with which patent medicines seemed to succeed each other in public favor. Surely, he thought, this quick turnover will make the public suspicious of advertising claims.

With the press of the claims from quackery, nostrum vendors, false medical theories, and uneducated therapists, such as the "natural bone-setters," Hooker had the unpleasant duty to admit that it was "not easy to distinguish between good and bad practice by results."[13] He did believe that over time the skillful practitioner had a better record for death and morbidity than the poor practitioner or quack but, regretably, "in order to discover this difference between skillful and unskillful practice, the observation must be extended over some length of time, and quite a large number of families."[14] He recognized that for the lay public, the choice of a good physician was not easy. He made a strong recommendation that a patient seeking a physician should inquire into the physician's education, the unbiased opinion of the physician held by his colleagues, and especially, "observing his mental qualities as they are exhibited in relating to those subjects which the observer himself understands."[15] By observing the habits of a physician in any of the day's common frustrations or his judgment as a citizen, neighbor, or member of an association, you can guage fairly well his habits in confronting disease, for "no man has different habits of observation for different subjects."[16]

To combat all these difficulties for the skilled physician, Hooker looked with hope to the formation of the American Medical Association and its promulgation of a Code of Ethics. The AMA would, he trusted, promote medical education, correct fallacious means of estimating professional merit, and obtain strict observance of the rules of interaction among physicians. The latter, which the Code of Ethics explicated in some detail, was crucial in the competitive health market of the 19th century, for unfair and dishonorable methods of obtaining patients was not that uncommon even among educated physicians. The code of ethics would unite physicians and protect the whole against the destructive impact of rival schools of thought and simple quackery. Illustrating the level of struggle for patients, Hooker even suggested that a patient, when visited by a physician who was a friend, avoid conversation on his or her ailment.

In broader matters, Hooker strongly advised telling the truth to patients, and certainly criticized telling any falsehoods. In this he departed from the position of Percival, whose essay on medical ethics allowed falsehood under certain extreme conditions.[17] Without being aggressively dogmatic, Hooker argued persuasively that patients can tolerate much more truth about their condition than physicians commonly assumed. He also pointed out the loss of confidence when the falsehood was eventually detected. The farthest he would permit interference with full disclosure was to withhold the truth but not to put falsehood in its place.[18] Hope should never be suppressed, and recovery was always possible.

The moral influence of physicians upon their patients and in their community was eloquently discussed in *Patient and Physician,* and the high standard he urged for physicians included temperance in alcohol, associations, and activities. He summed up the medical life by balancing its trials and pleasures. The pains were various. The physician is often exhausted by his labors; he is the last person to be paid among a patient's creditors, is subjected to the spectacle of the quack and patent medicine proprietor amassing wealth, and is sorely tried when even the educated brethren stoop "to an occasional use of the arts of the charlatan."[19]

Especially galling to Hooker were the clergymen who usually were treated gratuitously, but then failed to show their gratitude by giving moral support to the medical profession. Hooker gave a word of admonition to the clergy. Too often they gave testimonials to patent medicines, or joined new medical cults, or became the patron of a practitioner whose only qualification was that he belonged to the clergyman's sect. Free treatment of some poor could be tedious also, and here Hooker frankly admits that with ungrateful and obnoxious patients "the romance of doing good will not stand this trial."[20] He certainly does not refer to the poor generally, for the "virtuous poor" are among the most grateful and rewarding to treat of any group, but the "shiftless poor" and particularly the "vicious poor" are a trial to a physician's benevolence. He should continue to treat, but he must steel himself to do his duty and not rely on gratitude or a changed lifestyle as a result of medical care and advice. On top of all these problems, physicians do not receive the general respect from the community which is accorded to educated clergy and lawyers. When sickness comes, the public is as likely to take a "secret nostrum" or go to "some pretender, of whom perhaps they know little else, than that he calls himself a German, and has an abundance of hair about his visage."[21] Hooker's chief complaint was that medicine was not taken seriously, and he set out, through education, example and organization, chiefly the new American Medical Association, to rectify the situation.

As one might expect from such a cheerful analyst, Worthington Hooker believed the pleasures of medicine

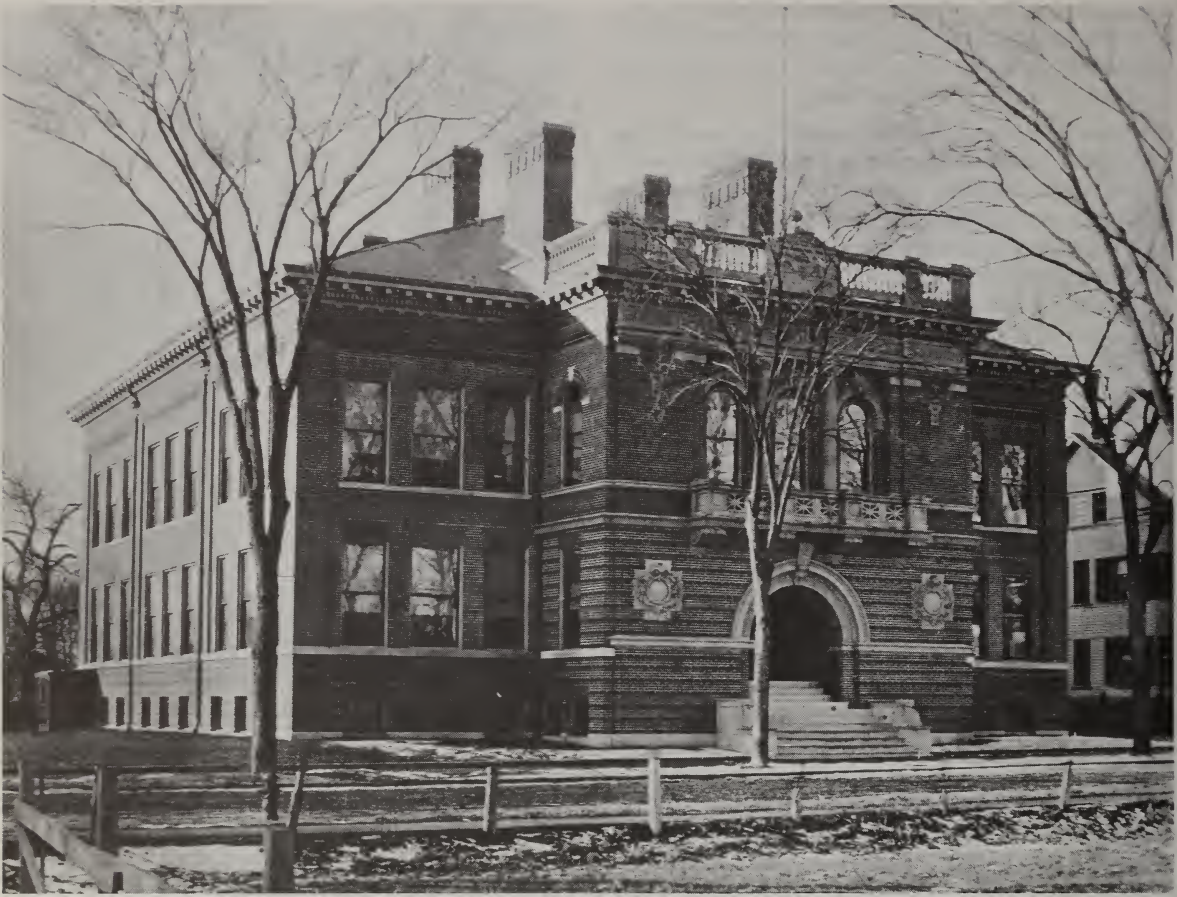

Figure 2
Worthington Hooker School (1939) New Haven, CT. *Courtesy of the New Haven Colony Historical Society.*

outweighed the pains. The attraction of medicine consists in its study of the remarkable human body. His attitude toward science and religion, the chief animating forces in his own being, shines through his description of the body:

> The physician looks upon the human body, not merely as a machine filled with contrivances so cunning and elaborate, as to render all the mechanism of man in the comparison crude and bungling; but as a machine instinct with life, having a living nerve attached to every fibre of it, giving it the power to act; and, more than all, as a machine holding in strange connection with its every fibre a reasoning soul, the image of the Deity, destined not to perish like the mind of the brute with the perishing body, but to live through the ages of eternity. [22]

To discover, then, some new fact which promotes the science of medicine and the health of mankind is an enormous joy; so is the gratitude of those who have been aided. Furthermore, as one who exerts a strong influence over the conduct as well as the health of others, the physician can himself feel gratified by the results of this influence. His familiarity with persons in all stations of life provides not only a unique view of society, but is also a source of understanding of human development and variation. This kind of experience also makes the physician a welcome companion, a warm and faithful friend, and "imparts an ease and zest to his conversation . . . and an abundance of facts and anecdotes to illustrate every remark which may be made." [23] This comprehensive catalogue of the merits of medical practice makes "the practice of medicine, when pursued with right motives, as a noble profession, and not as a trade, to be in the main eminently satisfactory and delightful." [24]

The Educator

Besides raising the status of medical practice, another goal was to revolutionize the teaching of science in the schools and colleges. Fascinated by natural science and eager to inspire others, he was disappointed by the meagre time spent studying such subjects as zoology and physiology in elementary school and college. Furthermore, what little time was devoted to natural history was deadened by memorization of facts and a lack of direct involvement with nature. He took the neighboring college as an illustration of this neglect:

> When a young man, for instance, enters Yale College, he is not supposed to know anything of the

> natural sciences, or at least no knowledge of them is required as a qualification for admission. After his admission, he is drilled in mathematics and languages alone for two long years. The natural sciences are wholly excluded til his junior year, when he begins to attend to Natural Philosophy, and in his senior year he is taught, necessarily in a very hurried manner, in Chemistry, Mineralogy, and Geology. Yale College by no means stands alone in this respect, for very nearly the same is true of most of the colleges in this country, showing how little importance is attached to the study of the natural sciences as a part of the system of education.
>
> All this is *radically* wrong.[25]

Hooker wanted the natural sciences introduced very early in a child's education and on a footing of equality with other subjects. At all times he wanted to emphasize the joy of study, direct contact with nature, and the spirit of inquiry. Memorization he placed well into a secondary role.

Hooker adduced several reasons to allot a major role to the natural sciences. Anyone involved in agriculture should know about the animal and insect world, he argued, and any educated citizen needs to have basic information on physiology and zoology. His somewhat more abstract argument, a favorite among professional educators, was that studies of the natural sciences are "essential to a *symmetrical* mental development, for when they are neglected the observing powers are not duly educated."[26]

Dr. Henry Bronson, a prominent New Haven County physician and writer on medical subjects, particularly local medical history, and a contemporary of Hooker's, reported that Hooker's "success in the difficult process of simplifying and unfolding scientific truth, and communicating it, in an intelligible and attractive form to the minds of children was conspicuous, a friend says, marvelous."[27] *Human Physiology* was published in 1854 and in the succeeding eleven years were published *Child's Book of Nature* (1857), *Child's Book of Common Things* (1858), *Natural History* (1860), *First Book of Chemistry* (1862), *Natural Philosophy* (1863), *Chemistry* (1863), and *Mineralogy and Geology* (1865).[28] The texts were very popular and several were in print more than two decades after his death.

Appropriately, in 1900, a public school in New Haven was named in honor of Worthington Hooker. This school thrives and is a center of neighborhood activity, uniting the efforts of parents and teachers in an active educational program. Dr. Hooker would be pleased with this living example of his philosophy. Interestingly, early in this century another great medical teacher, Dr. Benjamin Spock, attended Worthington Hooker School and recalls vividly "I *loved* it."[29]

Dr. Hooker wrote widely for many kinds of journals. He was reviewing Maudsley's *Physiology and Pathology of the Mind* when he had to stop work due to his final illness, a fever which within a few days took his life. He broke off his review with the comment: "There are many other parts and points of this author which we had intended to touch upon, but sickness has cut our duties short."[30] Hooker died on the 6th of November, 1867, in his 61st year. His demise was a great shock to the community for, until this ailment, he had been in his usual ebullient health.

Hooker's first wife had died shortly after their move to New Haven. On January 31, 1855, he married Henrietta Edwards, the daughter of a former governor of Connecticut. They had one son, Alfred Edwards Hooker, born January 6, 1857. He graduated from Yale in 1880 with the BA degree and remained to obtain a Bachelor of Philosophy in 1882 following two years of graduate work in biology. He then attended the College of Physicians and Surgeons in New York, where he received his MD in 1885. Further post-graduate work at the Presbyterian Hospital in New York gave great promise of a career perhaps as remarkable as that of his late father. Regretably, he contracted diphtheria from a patient under his care and died on the 27th of April, 1887, at the age of 31.[31] Henrietta Edwards Hooker died in New Haven at the age of 79 on January 16, 1894.[32]

Worthington Hooker served his profession in the noble manner he recommended to others. I warmly suggest a careful reading of *Physician and Patient* to anyone interested in Hooker's philosophy. The prefaces to his textbooks are also eloquent statements of his views on education and the importance of scientific knowledge. He was particularly keen on reaching the minds of young children and keeping alive their sense of wonder and discovery. We are all, in one way or another, indebted to him, and we should take care that his achievements not slip into oblivion.

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Rules of Behavior for Yale Medical Students, Published 1815.

SECTION VII. *Crimes and Misdemeanors.*

ART. I. Every Medical Student shall be subject to the laws and government of the Medical Institution, and shew, in speech and behaviour all proper tokens of reverence and obedience to the Faculty of the College, as well as of the Medical Institution. And if any Student shall transgress this law, by treating them, or any of them, with reviling or reproachful language; or by behaving contumaciously or contemptuously towards them, or by being guilty of any kind of contempt of their persons or authority, he may be punished by any censure, even to expulsion, as the nature and aggravations of his crime may require.

2. If any Student shall deny the Holy Scriptures, or any part thereof, to be of divine authority; or shall assert and endeavor to propagate among the Students any error or heresy, subverting the foundation of the Christian religion and shall persist therein after admonition, he shall be dismissed.

3. If any Student shall be guilty of Blasphemy, robbery, fornication , theft, forgery, duelling, or any other crime, for which an infamous punishment may be inflicted by the laws of the State, he shall be expelled.

4. If any Student shall assault, wound, or strike, the President, a Professor, or a Tutor, or shall maliciously or designedly break their windows or doors, he shall be expelled.

5. If any Student shall be guilty of drunkenness, fighting, striking, quarrelling, challenging, turbulent words or behaviour, wearing women's apparel, fraud, lying, defamation, or any such like crimes, he shall be punished by admonition, or other Collegiate punishment, suited to the nature and demerit of the crime.

6. If any Student shall break open the door of another, or privately pick his lock with any instrument, he shall be admonished or otherwise punished, as the nature of the offence may deserve.

7. If any Student shall be guilty of any injury to a fellow-student, or to any other person within the town of New-Haven, upon complaint and proof thereof made to the President, he shall, with the advice of the Professors, give judgment thereon, and order satisfaction to be made according to the nature of the offence or injury; which, if any student refuse to do, he shall be admonished; and if after admonition, he persist in such refusal, he shall be dismissed.

8. Every Student, in studying time, shall abstain from hallooing, singing, loud talking, playing on a musical instrument, and other noise, in and about the Medical College, or any of the College Buildings.

9. No Student shall keep, or use fire-arms, or gunpowder, in, or near any College Building, or near the person, or dwelling, of any officer of the College.

10. No Student shall stake money, or other property, in any game of hazard, or play at such game at all, within the College Buildings, or within the city of New-Haven, or any Student's room, or keep cards, or any instruments of games of hazard in his chamber.

MAGNETIC RESONANCE IMAGING
Where Did It Come From? What Is It? Where Is It Going?

Part I
History and Physical Principles

HAROLD B. HAWKINS, M.D., M.P.H. AND DOROTHY C. CINTI, M.D.

**Sagittal MR image of the head courtesy of General Electric Medical Systems.*

History and Physical Principles

Recent years have witnessed an endless array of amazing technological advances in medical imaging. One of these, magnetic resonance imaging, is truly one of the greatest achievements of man and will, in coming years, have a profound impact upon the practice of medicine and radiology.

While considering the questions we all have about magnetic resonance imaging, the theme of a Tahitian painting by Gauguin came to mind. The title of the painting is “Where do we come from?, What are we?, Where are we going?”. The intent of this paper is to give some answers to these same questions regarding magnetic resonance imaging. Where did it come from? What is it? Where is it going?

Where did it come from? Magnetic Resonance (MR) has been going on for a fairly long time. It is a well-established phenomena of some 40 years’ duration. The discovery of it was a fascinating coincidence in that it was discovered in 1946 by two totally independent groups simultaneously. One worked under the direction of Bloch at Stanford University and the other under Purcell at Harvard. Without knowledge of one another’s work they reported their results in two consecutive issues of Physical Review. In 1952, they were jointly awarded the Nobel prize in physics for their discovery. Since that time, magnetic resonance has been an important tool in chemical laboratories. However, it was not until 1973 that the principles of magnetic resonance were first applied to imaging. This was done by Lauterbur working at the State University of New York in Stony Brook. The first image which Lauterbur produced, just 11 years ago, was a cross sectional image of a test tube filled with water. Since this first significant, although rudimentary image, the progression of MR technology has been astonishingly rapid. In the late 1970’s animal images created considerable excitement. Today, only a few years later, we are seeing startling images of the entire body. Not only is this modality capable of producing images with exquisite anatomical detail and unequaled contrast resolution without any known harmful biological effect, but in addition, the body can now be directly imaged in any plane. In fact, it can be imaged in multiple planes simultaneously.

That’s where MR came from. Now—What is it? How are the images produced? It’s a rather fascinating phenomenon. It is a technique of imaging using the physical principle that many atomic nuclei have magnetic properties. In the body, hydrogen is by far the most abundant. For all practical purposes it is hydrogen protons which are currently used in imaging and it is the hydrogen proton which will be described in this discussion.

You might look upon hydrogen protons as if they are little spinning basketballs, each of which has a magnetization of its own, like a bar magnet. If left to their own devices these spinning protons would be randomly oriented. However, if they are placed into a strong external magnet, the protons will line up in the same direction as the external magnetic field. With MRI, the body is placed into a large magnet. The hydrogen protons within the body act like weak bar magnets and line up with the north and south poles of the strong external magnet.

To go back for a moment, the movement of the protons is a little more complicated than a simple spin. They behave much like a top. They do spin like a top, but in addition, they also have a rotating motion which is called precession. (Precession is the slow rotational movement of a spinning body around a vertical line so as to describe a cone. Think of a spinning top which is tipped off its vertical axis . . . it spins and also rotates or precesses around the axis.) In essence then, we have a proton which is spinning and also rotating or precessing. The rate of this precession, or its resonant frequency, lies at the heart of MR imaging. There is a direct relationship between the rate of precession, that is, the resonant frequency, and the strength of the external magnetic field. This relationship is defined by the Larmor equation ($W = \gamma\beta$). It says, very simply, that the rate of precession, or resonant frequency, is equal to a constant times the strength of the external magnetic field.

How is this knowledge of this resonant frequency used? This is where radio frequency waves come into play. If one gives a radio frequency pulse of exactly the same frequency as the resonant frequency or rate of precession of the protons, the protons will become excited, that is, they will absorb energy. It is analogous to the situation with tuning forks. If you have two tuning forks of exactly the same frequency and bang one of them, its vibrations will make the other of the same frequency resonate.

When the radio frequency pulse is applied and the precessing protons absorb energy, two things happen: 1. the protons all start to precess in unison or in phase and 2., their angle of precession is increased, that is to say, the protons are tipped down, let us say to 90°. This results in a net magnetic vector which rotates at 90°. For instance, if we have two protons prior to the radio frequency pulse, they precess at the same rate but are in different phases of the cycle. With application of the radio frequency pulse they join each other in the same phase of precession and are tipped down producing a rotating magnetic vector. This rotating magnetic vector is the source of the MR signal. From high school physics we remember that a magnet which moves through a coil will induce current in that coil. With MR the rotating net

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magnetic vector of the excited protons cuts a receiver coil, inducing a current within it. The strength of this current is the strength of the MR signal. That is how the signals are produced.

In summary, you have millions of tiny nuclear magnets, that is, protons, spinning and precessing inside the body. The body is placed into a large external magnet. The strength is on the order of eight times that of a magnet used in junk yards to pick up wrecked cars. Immediately surrounding the body is a coil which has a dual function. The coil delivers the radio frequency pulses which are somewhere between the AM and FM bands on your radio dial and are applied in millisecond bursts. It also acts as a receiver coil for the emitted energy.

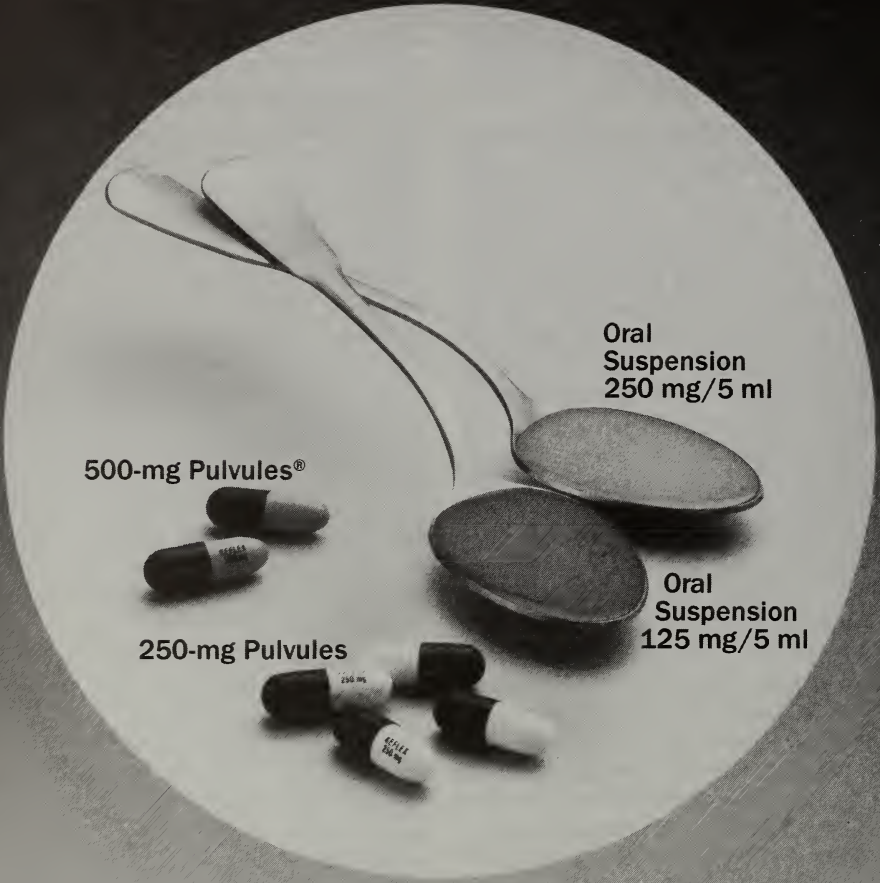
By now you may be asking yourself if MR signals are produced by hydrogen protons which are scattered throughout the body. How do you know what signal comes from where or how are the signals localized in space? To explain it we have to go back to our one equation which you will recall, equates resonant frequency, that is, the rate of precession of the protons, with the strength of the external magnetic field. To determine what signal comes from where a clever way of encoding signals has been developed. This is accomplished by varying the magnetic field strength of the external magnetic field. The magnetic field gradient is made to increase in strength from one side to the other. Within this gradient are hydrogen protons which precess at a rate proportional to the strength of the field in which they lie. On one side the protons in a weak field resonate slowly and on the other side those in a strong field resonate rapidly. Thus we have a means of spatially encoding information. The lower frequency signals which are given off come from one side and the higher frequency signals come from another side. An example closer to home is that of your radio tuner. You know that WTIC at 1080 kilohertz comes from Hartford and that WKND at 1480 kilohertz comes from Windsor. By turning your radio dial you are in effect localizing or spatially decoding the geographic origin of the signals.

That is how the signals are produced and located in the body but one last principle needs to be mentioned—that is, what makes one tissue look different from another. This depends of four different parameters. One of course, is the proton density or simply, the number of protons in any volume of tissue. Where there are a lot of protons there is a strong signal and a white image. Another parameter is the flow, or the speed of movement of the protons through a volume of tissue. Blood, which moves rapidly, will exit from a volume of tissue before a signal can be recorded from it, hence its protons will give no signal and a vessel will look black. Finally, there are these mysterious things of which some of you have already read and of which we will all read about with increasing frequency in coming years—these are the relaxation times T_1 and T_2. For each hydrogen proton these vary according to the chemical and physical environment of that particular proton. To repeat—for each proton the T_1 and the T_2 vary according to the chemical and physical environment of that particular proton. Because of this T_1 and T_2 give tissue discrimination.

Unfortunately, the full explanation of T_1 and T_2 is very complicated, but to explain them briefly—when the radio frequency pulse is applied and the protons are tipped down 90° all of them precess in unison producing a net magnetic vector at 90°. After the radio frequency pulse is turned off, there are two processes which occur as the protons relax and give back the energy they have absorbed. These are defined by the relaxation phenomena called T_1 and T_2. First to be discussed is T_2. With time, the net magnetic vector which is precessing at 90° and cutting the radio frequency coil and giving off a signal, gets shorter and shorter and shorter and ultimately goes to zero. This is because the net magnetic vector is produced by multiple protons precessing in phase. Gradually they get out of phase with each other and the signal dies away. The time this takes is referred to as T_2. T_1 is easier. It is simply the time it takes for the net magnetic vector to return to its original orientation in the magnetic field.

The T_1 and T_2 components of an image can be independently emphasized or de-emphasized by varying the delivery time and duration of the radio frequency excitation pulses. These variations, which are potentially endless, are referred to as pulse sequences. Depending upon the pulse sequence selected, and therefore, the emphasis placed on T_1 or T_2, a given image can be dramatically altered in appearance. An area white with one particular sequence of radio frequency pulses can be made to appear black or gray on another by simply changing the timing of the radio frequency waves, that is, by changing the pulse sequence. By exploiting these differences, one can discriminate between different tissues. Those are the basic principles of magnetic resonance imaging.

Easy To Take



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MAGNETIC RESONANCE IMAGING
Where Did It Come From? What Is It? Where Is It Going?

Part II
Clinical Applications

DOROTHY C. CINTI, M.D. AND HAROLD B. HAWKINS, M.D., M.P.H.

Clinical Applications

The end product of MRI is, of course, an image, but to say it is only an image is an enormous understatement. "MRI combines the advantages of other imaging modalities without sharing their disadvantages."[1] There is no ionizing radiation and no known biological hazard. The spatial resolution is excellent and contrast resolution is superb. By way of comparison soft tissue contrast with CT is on the order of 7% and with MRI it is 500%.[2] The body can now be imaged in virtually any plane without reconstruction, in fact, in multiple planes and with multiple slices simultaneously.

The initial clinical application of MRI was in the CNS, but its applications currently cover the entire body, literally head to toe. Let us now go through the body with Magnetic Resonance Imaging starting with the central nervous system.

Central Nervous System

In the brain, multiple sclerosis was one of the first diseases in which the great potential of Magnetic Resonance Imaging was demonstrated. Indeed, it is now clear that for evaluation of demyelinating processes MRI is unequalled.[3]

What about other CNS processes? MRI has already proven itself to be more sensitive than CT in tumor detection[3,4] as well as in evaluation of extra-axial fluid collections.[3] MRI provides earlier identification of brain infarcts and more accurate delineation of the extent of damage.[3] Due to the lack of signal from rapidly flowing blood, vascular lesions such as some arteriovenous malformations and aneurysms can be dramatically demonstrated with no need for either intravenous contrast enhancement or catheter manipulation.[3]

Unlike CT, with MRI bone does not cause any beam hardening artifacts. As a result of this, posterior fossa lesions which are often difficult to visualize on CT, are readily demonstrated with MRI.[5]

This lack of bone artifact as well as MRI's ability to image directly in any plane without the need for reconstruction provides visualization of many areas of the body which were previously difficult to see well. One of these areas is the brain stem. At the present time, MRI is clearly the examination of choice for evaluation of brain stem abnormalities.[6]

For some time myelography and, more recently, CT have been the accepted modalities for visualization of the spinal cord. There is reason to believe that for many diseases MRI will replace those exams because the spinal cord can now be directly visualized in all planes noninvasively.[7] (Figure 1) MRI affords exquisite visualization of abnormalities in the region of the foramen magnum, of the Arnold-Chiari malformation and syringomyelia. It provides invaluable information in the presence of spinal trauma. Spinal canal blockage can be assessed without the need for contrast from above or below.[7,8]

The returns are not yet in for the role of MRI in discogenic disease. However, it holds great promise. The normal nucleus pulposus gives a bright white signal whereas the surrounding annulus gives relatively less signal and is dark. A degenerated nucleus loses signal intensity, becoming black. Only degenerated nuclei herniate. In some instances the herniated disk fragment can be identified pressing directly upon the dural sac.[7] (Figure 1)

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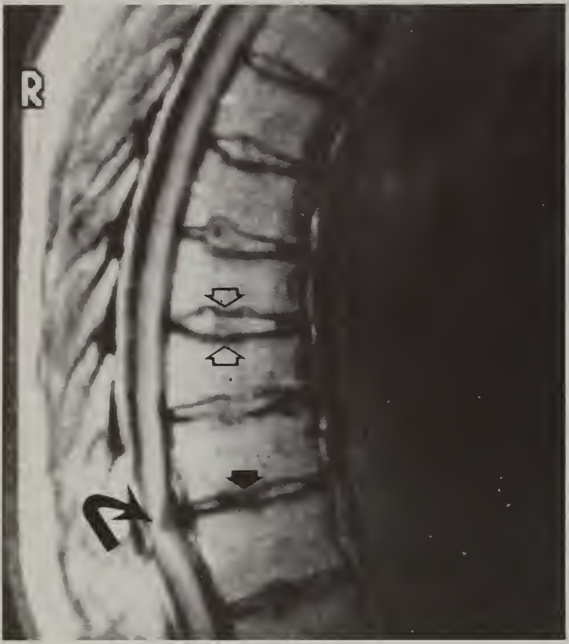

Figure 1
Midsagittal MR image of the spine provides direct visualization of the spinal cord. The normal nucleus pulposus is shown here as white (open arrows). A degenerated nucleus pulposus is dark (closed arrow) and at the same level a herniated fragment presses upon the cord (curved arrow). *(Courtesy of Philips)*

Cardiovascular System

Because the cardiac chambers and great vessels are filled with rapidly flowing blood, no signal is recorded from them and because they are surrounded by air-filled lung which doesn't have any protons to give signal, cardiac and vascular walls stand out in bold relief against a sea of black. It is somewhat disarming how much the internal topography which can be seen on scans obtained with cardiac gating resembles a cadaver section. The size of the cardiac chambers, thickness of the ventricular walls and interventricular septum, papillary muscles, even the cardiac valves and coronary arteries are delineated.[9] (Figure 2) The pericardium and pericardial abnormalities are exquisitely demonstrated.[10]

Localized wall thinning due to prior myocardial infarction, intracardiac thrombi and regions of turbulent blood flow are directly visualized.[11] In the presence of acute ischemia, damaged muscle has a different T_1 relaxation time than does normal muscle providing the potential for delineation of an acute myocardial infarction.[9]

Cardiac motion studies are possible and the multiplanar facility of MRI provides the ability to evaluate ventricular function, ejection fractions, and localized ventricular wall abnormalities.[12]

Take a look into the future . . . consider taking a patient with an acute myocardial infarction and then performing an MRI motion study. With one noninvasive exam you can see the area of acute ischemia, see any region of thinning from an old infarction, identify areas of abnormal wall motion, and determine the ejection fraction. Will this become practical? Time will tell.

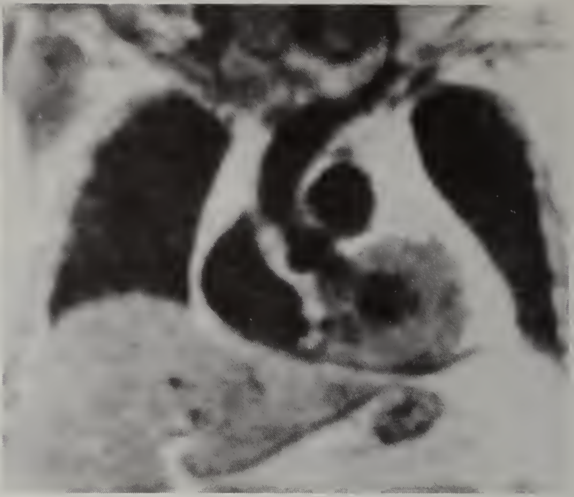

Figure 2
Coronal MR image of the chest delineates the internal morphology of the right atrium and left ventricle as well as the ascending aorta and pulmonary artery. The left ventricular wall is thickened due to a cardiomyopathy.

Note the concomitant direct visualization of the liver in the coronal plane. *(Courtesy of Siemens)*

Due to the absence of signal from rapidly flowing blood, vessels are well seen and patients with question of coarctation, interruption of the aorta, or dissection can be worked up without angiography.[9] (Figure 3)

In contradistinction to rapidly flowing blood, slowly flowing blood does give a signal. In fact, the intensity of the signal provides a means of quantitating the rate of flow. Needless to say, this facility has potential value in the assessment of the functional significance of atherosclerotic lesions as well as other processes which compromise vascular patency.

Atherosclerotic plaques themselves produce signals of low to moderate intensity depending upon the relative amounts of fat, fibrin, and clot within them. Plaques and/or clots are directly visualized within the vascular lumen.[13, 14]

Thorax

MRI is said to make the evaluation of hilar adenopathy a cinch. The normal hila are, of course, composed of vessels which give no signal due to flowing blood and bronchi which are filled with air and, therefore, have few hydrogen protons to give a signal. You can see why hilar adenopathy is so easy to detect. There isn't normally anything except the black tubes of the vessels and bronchi and the bright white of a little peribronchial fat in the hila.[15-17] As a result of this, tumor masses can be clearly differentiated from adjacent vessels and the extent of vascular invasion and/or displacement evaluated without intravenous contrast.

Likewise, in the mediastinum solid and/or cystic lesions are easily differentiated from vascular abnormalities.[15-17]

Breast

Although investigation of the potential use of MRI for breast disease is still limited, the modality has proved to be capable of detecting abnormalities seen on mammography. The configuration of a lesion on MRI appears to permit distinction between benign and malignant processes.[18] It remains to be seen whether it will be useful as a screening modality. Because of MRI's ability to provide soft tissue discrimination, there is hope that it may be able to detect small malignant and possibly even premalignant areas.

Abdomen

In the liver, MRI has proven to be at least the equal of CT in detection of tumor even without the use of respiratory gating.[19,20] With the addition of gating, it is likely to be even more sensitive. In addition, it offers the distinct advantages of clear delineation of vascular anatomy, direct coronal and saggital sections which provide precise preoperative localization of lesions, and it obviates the need for intravenous contrast.[19,20] (Figure 2)

In the biliary system, MRI offers unique advantages. Within the liver the adjacent branching portal veins and bile ducts stand out in bold relief against the liver parenchyma. By use of the proper pulse sequence, the different relaxation times of bile and blood can be used to separate the bile ducts from the portal veins.[21]

MRI provides similarly unique physiologic information regarding gallbladder function. Concentrated bile produces an intense MR signal and it layers out below dilute bile which gives a weak signal. In chronic cholecystitis the gallbladder cannot concentrate bile and, therefore, the signal remains weak.[21]

Kidney and Adrenals

Because the renal cortex and medulla have different T_1 and T_2 values, they can be clearly differentiated without the use of intravenous contrast materials. Likewise, without contrast, determination of the solid or cystic nature of renal masses and staging of tumor is at least equal to that of CT.[22,23] In addition, elegant direct delineation of tumor invasion of the renal veins and/or inferior vena cava is provided without angiography.[23] In evaluation of cystic lesions, MRI offers the unique asset of differentiating simple cysts from those which are complicated by hermorrhage or infection. This means that given a patient with multiple cysts, if there is also clinical evidence of infection, the infected cyst can be targeted.[22]

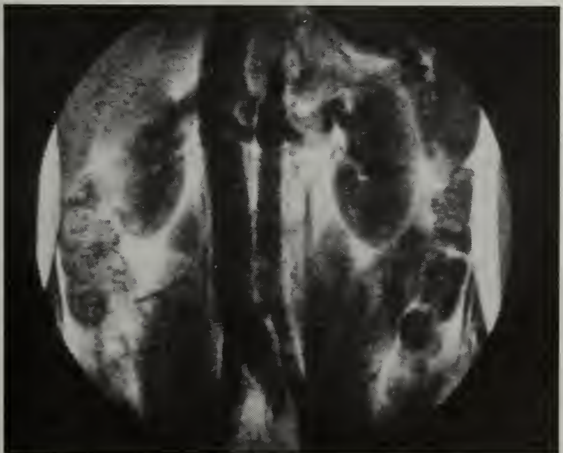

Figure 3
Coronal MR image of the abdomen demonstrates the inferior vena cava and aorta and their branches. The vascular lumina are visualized due to the absence of signal from rapidly flowing blood. *(Courtesy of General Electric Medical Systems)*

MRI appears to be a promising modality for evaluation of adrenal disease. It matches CT in detection of disease without ionizing radiation or intravenous contrast and in some cases offers the intriguing ability to differentiate the adrenal cortex and medulla.[24]

Pelvis

In the genitourinary system, the most significant impact of MRI so far has actually been in the pelvis where the natural contrast of fat, urine, air-filled bowel, flowing blood, and lack of respiratory motion are ideal for imaging with Magnetic Resonance.[25] (Figure 4) In the pelvis, one sees anatomy that none of us has seen since medical school: muscle bundles, fascial planes, and even neurovascular bundles never before imaged. The availability of direct coronal and saggital scans has provided information hitherto unobtainable. Needless to say, the lack of ionizing radiation provides an especially important benefit in this part of the body.

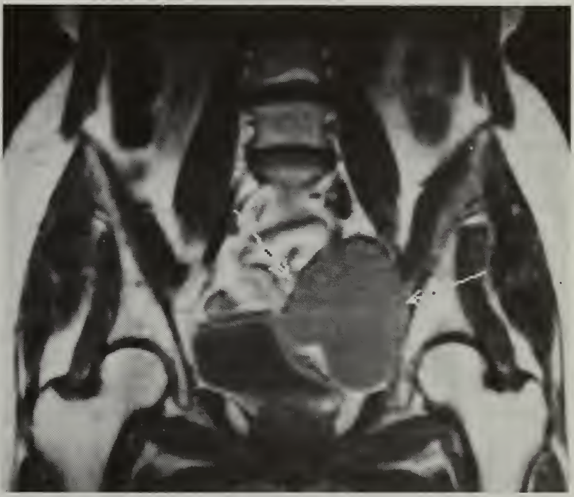

Figure 4
Coronal MR image of the pelvis shows a lymphocele (white arrows) pressing upon the left side of the urinary bladder. The fluid within these structures is of different signal intensity due to the difference in the relaxation times of lymph and urine, a phenomenon which provides for tissue characterization. The thickness of the bladder wall is defined and muscle bundles such as the psoas, iliacus, and glutei are sharply contrasted against the surrounding white signal of fat.

Note that the medullary spaces of the femura and innominate bones are clearly delineated with a strong white signal. This is due to fat within them. The surrounding bony cortices lack mobile protons and, therefore, give no signal and are black. *(Courtesy of Siemens)*

In the female pelvis, MRI provides differentiation of the bladder, rectum, uterus, cervix, vagina, and ovaries. The smooth muscle of the myometrium presents as a thick, gray outer band and is separated from the endometrium. In fact, two layers of the endometrium can be identified: the zona basalis, a dark band, and the zona functionalis, a bright white central band, which changes in width during the menstrual cycle. In the assessment of female infertility, the cyclical changes in the endometrium may provide useful information.[26]

In the male pelvis, another first for MRI: direct visualization of the prostate and seminal vesicles. In fact, multiplanar imaging affords assessment of the volume of the prostate. Disease confined to the gland such as small foci of prostatic carcinoma can be directly imaged. It remains to be seen whether these tiny neoplastic foci can be differentiated from prostatitis.[27]

At the current time, the best proven clinical utility of MRI in the pelvis is in the evaluation of the extent of tumor. With prostatic carcinoma, assessment of direct spread into the adipose tissue surrounding the prostate, the base of the bladder, and the seminal vesicles is anticipated. In the urinary bladder, the thickness of the wall is clearly seen, tumor mass is delineated and potentially even differentiated from concomitant benign thickening.[27] The availability of saggital and coronal images is especially useful for evaluation of the base and dome of the bladder which are difficult to evaluate with axial images and for delineation of extension of disease into the levator ani and perineum.[25]

Musculoskeletal System

Although the precise role of MRI in musculoskeletal disorders in general has not yet been extensively explored, this too is an area of great promise.[28-30] Because cortical bone lacks mobile protons, it gives no signal and is not visualized. However, the medullary space is clearly seen due to the fat and blood within it. (Figure 4) Consequently, lesions which infect the medullary space such as tumor, infection, aseptic necrosis, and even some bone marrow disorders can be delineated. Muscles, tendons, ligaments, nerves and vessels each have unique T_1 and T_2 relaxation times and, therefore, can be differentiated.

Conclusion

Are there any problems associated with MRI? Yes, a few. To date, it is costly. Furthermore, there is concern that strong magnetic fields may cause movement of aneurysm clips or trigger pacemakers. On a lighter note, it is known to erase magnetic credit cards, a definite worry for some of us.

The preceding has been a review of the best established medical applications of Magnetic Resonance Imaging to date, i.e. body imaging using hydrogen protons. But to return to the theme of Gauguin's painting. Where is MRI going? What lies in the stars? Yet to come is MRI body imaging of other less abundant magnetic nuclei such as phosphorus and sodium and the in vivo use of Magnetic Resonance Spectroscopy which has the phenomenal potential of providing chemical analysis and the mapping of metabolic functions.

In the stars is the fulfillment of this prophetic quote from Thomas Huxley 100 years ago: "What an enormous revolution would be made if physics . . . could supply means of making out the molecular structure of living tissues comparable to that which the spectroscope . . . affords into the nature of the heavenly bodies."

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At a Convention of the Medical Society of the State of Connecticut, October 1809, a Committee was appointed, to select pieces for publication, from such communications, as then were in possession of the Secretary, or should be made to them, and to publish them before the meeting of the next Convention-In pursuance of their appointment, a selection has been made, of such pieces, as in the opinion of the Committee, were best calculated to answer the design of the Convention.

The Committee regret, that from some of the Counties they have received no Communications, nor from several individuals, from whom they flattered themselves, that valuable medical information would have been received.

JOHN BARKER,
JOSEPH FOOT,
ELI IVES, COMMITTEE
THOs. GOODSELL,

New-Haven, September 1810.

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Measuring Economic Damages in Wrongful Death: The Case of a Physician

J. FREMON JONES, PH.D.

Contemporary society has placed a heavy burden of financial risk on today's physician, with plaintiff malpractice awards reaching truly astronomical levels. Like it or not, this condition is here to stay. There is no way the situation can be reversed since even legislation cannot stop the tide. Given that, you should be aware of the methodology used by economists to estimate damages in malpractice cases, and accidents resulting in wrongful death or personal injury. Although such knowledge will not lower your malpractice insurance premiums, it will help you to understand one of the reasons that they are so high.

The easiest way to describe the methodology is to cite an actual case. The case involves a 36-year-old plastic surgeon who died in a private aircraft accident. This case is particularly tragic in that his wife and daughter also died in the same accident.

I will call him Dr. Williams. Dr. Williams was very much an aviation enthusiast. He loved to fly. It was his recreation. He was an experienced and very careful pilot. The day of the accident could not have been more beautiful, a clear crisp autumn afternoon. He had had some maintenance performed on the plane earlier that morning, and had test-flown it before going home to pick up his family for a sightseeing flight along the edge of the mountains to view the fall foliage. The air around the mountains is frequently bumpy and rough, but today it was smooth as glass. Conditions could not have been better. Unbeknown to him, a critical wing strut fitting was overburdened with metal fatigue, having a microscopic crack in it. When he was alone in the plane there was no problem, but when the weight of his wife and daughter (plus the family dog) were added, the fitting gave way shortly after gaining altitude. The plane went into a spin with no possibility of recovery and no possibility of survival no matter how good a pilot he was. Accordingly, a product liability suit was filed against the manufacturer of the airplane on behalf of the estate of Dr. Williams.

It became my task to place a economic value on the lives of Dr. Williams, his wife, and daughter. The following analysis addresses only the doctor's earning capacity. The methodology for the wife and the child are similar, but use different assumptions.

The basic questions was: What could Dr. Williams have earned had he not died in the tragic accident? In legal jargon, what was his "earning capacity?" Most people don't realize the magnitude of the earning power of the average person, much less that of a physician. As late as the 1960's many courts would not let an economist testify to the economic value of a human being, because it was argued that the economist was "invading the province of the jury." Prior to the influence of economists, there had been a systematic underestimation of the true losses in wrongful death cases. The objective of our legal system is justice, and today, injured persons are more likely to find economic justice than ever before because the courts have realized the value of the economist's testimony.

The procedure for estimating what Dr. Williams could have earned seems complex, but the basic concept is fairly straightforward. Beginning with what he was earning at the time of his death, his annual earnings are projected into the future. Since he is no longer alive, the monies he would have spent on his personal needs are projected into the future. The consumption expenditure is then deducted from the lump sum value of the earnings, and the result is the amount of the economic loss.

What gives the loss credibility in the eyes of the courts is that when the analysis is conducted using acceptable statistical methods with valid data, the result is a reasonably accurate picture of what the person could have earned.

J. FREMON JONES, PH.D., Consulting Economist, Virginia Beach, VA.

The earning capacity analysis has two parts: first is the loss of earnings; second is the loss of the retirement benefits.

Analysis I—Earnings Loss

Dr. Williams had begun his practice about May, 1977, and had not had enough time to develop the full potential of his earnings from his practice. His taxable income in the year of his death was approximately $51,000. Needless to say, he was the principal economic resource for his practice, and when that was destroyed with his death, the practice was destroyed as well.

Information furnished me indicated that Dr. Williams was considerably above average in talent and skill. Nevertheless, for statistical purposes, the assumption will have to be made that he would have been an average plastic surgeon earning what the average plastic surgeon earns.

An analysis of a 1981 research study indicated that plastic surgeons earned a weighted average of $126,075.[1] Since Dr. Williams was earning $51,000 at the time of his death, it is clear that his earnings would have continued to increase in the future. The only question to be addressed is at what percentage rate would they increase?

Actually, there are two rates of increase involved. The first is that which would have occurred from the date of his death to some point in time, bringing his earnings up to the level of the average plastic surgeon. Research by the American Medical Association (AMA) indicates that a surgeon will reach the average for all surgeons about age 43.[2] Data for all surgeons had to be used since the AMA data did not divide the surgeon specialty into subspecialties.

Dr. Williams was 36.54 years of age at the time of his death. Therefore, it is assumed that 6.46 more years would be required for him to reach the average earnings of all surgeons. This means an average annual rate of increase of 15.09% per year to increase his income from an annualized base income of $50,844 at age 36 to reach $126,075 in earnings by age 43.

The second rate of increase in earnings is that achieved by the profession as a whole, over a long period of time. The best indicator of how much of a long term increase in earnings Dr. Williams could have expected to have received is found by referring to the statistical data generated by research on consumer prices. This continuing research by the federal government has a number of specialized indexes that examine the trend in prices of specific goods and services. One of these is the Index of Physicians' Services, which indicates the trend of physicians' fees. Looked at from the physician's point of view, it provides a good insight into what increase in income could be expected over the long run.

As of December 1982, the index stood at 339.9.[3] Using 1967 as the base year, this same index has a value of 51.4 in 1947. In other words, the cost of physicians' fees has increased 661.3% since 1947. The compound annual rate of increase over this period of 35 years is 5.46% per year. The overall increase in consumer prices over this period of time was 4.27% per year. This means that physicians' fees have increased an average of 1.19% per year more than consumer prices. Most of this increase can be attributed to an increase in physician productivity through the use of paramedicals, group practice, and the like. Not only can the 5.46% per year rate of increase be expected to be maintained, it will probably increase with the passage of time. Further increases will be caused by the aging of our population, attitudes toward medical care, and other structural components of our society and economy. However, there is no statistical basis for using a higher rate; so the 5.46% rate of increase must be used to estimate the rate at which Dr. Williams' income would have increased in the future over the remainder of his work-life.

Before a projection of future income loss can be made, a retirement age must be selected. Inasmuch as most physicians are self-employed, there is no mandatory retirement age. Most physicians continue to practice after the typical retirement age in society of age 65. Unfortunately, there has been little research into the question of the retirement of physicians. The one article on the subject takes the position that the vast majority of physicians tend to practice until such time as they feel that their skills are declining. It is not uncommon, according to the article, to find physicians working well into their seventies. In fact, March, 1980, statistics of the American Medical Association reveal that 25,000 of the 223,200 members were over 70 years of age.[4] This means that over 11% of the members were over 70 years of age. Dr. Williams was in good health, and could have expected to have lived out his normal life expectancy to age 73.3. Given this, it is reasonable to assume that Dr. Williams would have continued to practice until age 70.

Applying the foregoing methodology indicates that Dr. Williams could have expected to earn $11,930,346 over his career. This amount represents what may be called the "gross future earning capacity." Of course, there is the strong possibility that he could have earned considerably more, but it must be remembered that this type of analysis is one that is prepared for presentation in a court of law. Any undocumented heroic assumptions regarding what he could have earned will quickly be demolished by the defense leaving the economist without credibility in the eyes of the jury.

The gross future earning capacity overstates the actual amount of the economic loss because an adjustment has to be made to account for the time-value of money. Money has a time-value because it can earn interest. Because it can earn interest, a sum of money in hand today is worth more than a sum of money to be received at some point in the years to come.

The earnings of Dr. Williams would be spread over a number of years into the future; so it is necessary to adjust these earnings to show what they are worth today. The mathematical procedure for adjusting for the time-value of this future income is known as "discounting to present value." The procedure applies some rate of interest to the future earning amounts to reduce them to their value today. Actually, discounting to present value is just the reverse of compound interest. With compound interest, you start with an amount today and some years later you have a larger future amount because you receive "interest on interest." Discounting to present value is just the reverse of compound interest. You begin with the larger future amount and end up with the smaller beginning value, which is the present value. When the discount rate is applied to the gross future earnings loss, Dr. Williams' earning capacity has a value today of $5,152,659.

It is very important to note that this value represents cash earnings only. Nothing has been included for the value of the retirement benefits he would have received. This element of loss has a substantial value and it will be considered next.

Analysis II—Retirement Benefits

The principal method by which most unincorporated physicians provide for retirement is through the use of a "Keogh" retirement plan. This plan is a plan whereby a self-employed person places some percentage of annual taxable income into a restricted investment fund. The contribution is tax-free as is any income that is derived from the fund. Beginning in 1981, the Individual Retirement Account (IRA) method has also been allowed for contributions to a fund that are tax-free as contributions and income. Dr. Williams had not begun a Keogh plan, but had begun an IRA. The assumption will be made here that he would have had both a Keogh plan and an IRA in the future. This assumption is supported by several facts. First, an IRA had already been set up. Second, only about 10% of all physicians do not have some retirement fund.[4] Most physicians who do not have a private retirement plan are young and just getting their practice started. Therefore, there is no doubt that Dr. Williams would have shortly had similar plans.

Analysis IIa—Keogh Plan

Dr. Williams will be assumed to have made a contribution of 15% of his income up to the maximum amount of $15,000 per year beginning in 1981, and continued these contributions until retirement at age 70. These contributions are invested, and will earn an income that is tax-free. An important question is how much will the fund earn? Or, put another way, what percentage rate of return could be expected over this period of 30 years?

The rate of return that can be earned from the investment of a fund of money depends on a wide variety of factors. Some of these considerations are the risk entailed with the investment, the requirement for liquidity, and the cost of managing a fund of money. Generally speaking, the rate of return to be had on an investment is mainly associated with the risk factor. The higher the risk of loss of principal, the greater the expected return. Liquidity, or the ability to convert the investment into cash on short notice, also affects the rate of return. The longer it takes to get an investment converted to cash, the greater the rate of return should be. The cost of management is relatively high with small amounts of money, but generally runs about 1% of total assets in amounts in excess of $50,000; so for these purposes the management fee is imputed rather than computed directly.

In this type of analysis, a rate of return has to be estimated since the view is to the future. The selection of a rate of return for a retirement fund has to take into consideration the characteristics described above. The principal characteristic sought when investing retirement funds is safety of principal, or lack of risk. Liquidity is not an important characteristic since he will have ample income in the future, and therefore will not need to have access to the fund before retirement. Cost of management can be regarded as nil if there is little turnover in the investment portfolio. The type of investment selected must take these characteristics into consideration.

Perhaps the best vehicle that meets the criteria for such an investment fund is United States government long term bonds. Their characteristics meet the foregoing requirements without question. In fact, it is quite possible for the fund to be invested in common stocks, real estate, and other types of investments that would provide a higher rate of return with only a modest increase in risk, but this type of research requires that the most conservative stance be adopted.

Given that United States bonds are to be used as the investment for the retirement funds, what rate of return can be expected? Bonds general return a fixed rate of return over the period of years that they are issued. These fixed issuing rates do fluctuate. This interest rate that a given bond earns depends on the economic conditions that exist at the time it is issued. That is, if the Federal Reserve System (Fed) is trying to bring inflation under control, it may have caused interest rates to increase to high levels. Thus, if the federal government wants to issue bonds during these times it will have to pay a higher interest rate than it would if the Fed were not following a "tight" money policy. Bonds are issued every year at rates of interest that prevail at the time.

However, all of the bonds that are outstanding actually yield about the same interest rate regardless of their face interest rate because of what might be called the "arbitrage" effect. The reason is that if there were different rates of interest, then investors would clamor for the higher interest rate bonds. There would be too many investors for a given bond issue; so they would bid up the price of the bond, and the net yield (interest rate) would come down. When this process is carried out throughout the bond market, the overall yield on all bonds ends up being about the same. Thus, interest rates in the bond market fluctuate with economic conditions and with the current monetary policy of the Fed.

It is impossible to predict or project the rise and fall of interest rates over the years; so the next best thing would be to use an average interest rate that had occurred over a number of years. If it is then assumed that the events that occurred over that period of time will repeat themselves, then it is reasonable to expect the same average rate of interest to occur over the same period of time in the future.

In recent years, we have witnessed wild oscillations in all interest rates. The economy has experienced "double digit" long term US bond rates since 1980. While these rates have come down some, the pattern seems to be that we are likely to continue to experience high interest rates for many years in the future. The average interest rate that has occurred in long term US bonds since 1974 is 9.16%. I have elected to make the assumption that the retirement fund would be able to earn at least 9.16% per year over its period of accumulation. It is my considered opinion that this interest rate would be able to be maintained throughout the term of the fund, and very possibly exceeded.

Contributions to the retirement fund of 15% of earnings up to $15,000 are set aside on an annual basis, then compounded by the 9.16% rate of interest for the years the fund would be in existence. By the time Dr. Williams reached age 70, he would have contributed $498,638 to the fund. With compound interest, the fund would have accumulated a total value of $2,865,725. What makes the amount so large is the 34-year period that the fund would be in existence, the fact that interest is compounded annually, and is income tax-free. It would be even larger if more frequent compounding were used. The annual amounts comprising the total are then discounted back to present value just as the earnings were discounted. The present day value of the Keogh retirement comes to $650,421.

Analysis IIb—Individual Retirement Account

It was stated earlier that Dr. Williams had an IRA account already established at the time of his death. It will be assumed that he would have continued to contribute to the fund to the maximum amount of $2,000 per year.

These annual amounts are continued at the same level from the date of his death until retirement at age 70. A total of $68,000 would have been contributed to the fund. Accumulated compound interest would have increased the fund to a total of $407,994 by the time he reached age 70. Discounted back to present value, the IRA fund is worth $92,600 today.

The sum of the values cited earlier overstate the true value of the economic loss. The amount of money he would have spent on himself to be able to continue to work has to be taken into consideration. These expenses are known as personal consumption expenditures.

Consumption

Had Dr. Williams lived, he would have had to spend a certain amount of money on food, clothing and shelter in order to remain healthy enough to produce an income. Since he is now deceased, it will not be necessary to expend these funds. Therefore, they do not represent a loss to him or his estate. Because these personal maintenance costs are part of the cost of generating an income, they must be deducted from what Dr. Williams would have earned just as the expenses of operating a business must be deducted from its gross income.

Personal consumption expenditure is that minimum amount of products and services required to maintain and sustain a human being in a healthy enough physical condition to continue to earn an income. Research of the U.S. government indicates that the minimum income needed to sustain life in 1980 was $5,551. Because we are dealing with a physical amount of products and services, the dollar amount needed to offset personal consumption expenditures will have to be increased each year to offset long-run increases in the price level. If 1967 is used as the base year, it is found that the long-run rate of increase in prices is expected to be 4.27% per year.

Therefore, beginning with 1980, the personal consumption amount is increased by 4.27% per year to offset the long-run increase in prices until Dr. Williams' estimated natural death. Over the years, a total of $411,449 would be required for personal maintenance. The same 4.90% discount rate used earlier is also used to reduce the annual gross consumption expenditures to present value which is $193,064.

Conclusion

The entire analysis now can be summarized and conclusions developed. The procedure is to subtract what the doctor would have spent on his personal needs from what he could have earned over the years to arrive at the amount of the net economic loss. Table 1 summarizes the foregoing analysis.

From the foregoing, it is found that Dr. Williams would have earned over $15,000,000 during his lifetime. The present day value of this loss of income is about $6,000,000. It is important to note that nothing has been included for any salary income he may have earned by working for a hospital or other such agency or the fringe benefits other than retirement. These elements can sometimes be substantial. To the extent that these elements are not included in the research, the values generated above underestimate the actual amount of the loss.

Table 1
EARNING CAPACITY & ECONOMIC LOSS
JOHN DOE WILLIAMS, M.D., DECEASED

	Gross Amount		Present Value Amount	
Practice earnings		$11,930,346		$5,152,659
Retirement Benefits				
Keogh fund	$2,865,725		$650,421	
IRA fund	407,994		92,600	
Total		3,273,719		743,021
Total		$15,204,065		$5,895,680
Less Consumption		411,449		193,014
Economic Loss	Gross	$14,792,616	Net	$5,702,616
				..... or say $6,000,000

Aside from the fact that it is interesting to understand the value of the earning capacity of a physician, there are several other valuable lessons to be learned from this research.

The first is that should someone in your family or someone you know be injured or killed in an automobile accident, you should seek competent legal counsel; and do not settle for too small of an amount. When I say "competent legal counsel," I mean: Find the best lawyer who specializes in representing plaintiffs in wrongful death and personal injury cases. Your family attorney will not do. The reason is obvious, recovery for wrongful death or injury has become very complicated, and thus requires a person of considerable experience to achieve a just economic damage award much less for pain and suffering. Also, if the attorney has a reputation with the defense counsel as presenting a well prepared case, the defense will be more inclined to settle for an amount that will more closely approach the economic damages than would otherwise be the case.

Lastly, and perhaps most important, be sure you carry enough automobile liability insurance. Should you become involved in an accident and kill someone—or worse, disable them for life—the damage award could ruin you financially. Consider this: The average young person with a high school education has a value of earning capacity in excess of $500,000! If you disable that person, he must receive institutional care for the rest of his life, you can be looking at a damage award of up to $5,000,000! You should talk to your attorney or financial counselor to verify that you are adequately covered by liability insurance. A good rule of thumb would be to carry, at the very minimum, liability insurance equal to your net worth. This way should a disaster of this magnitude befall you, all that you have worked for will not be lost.

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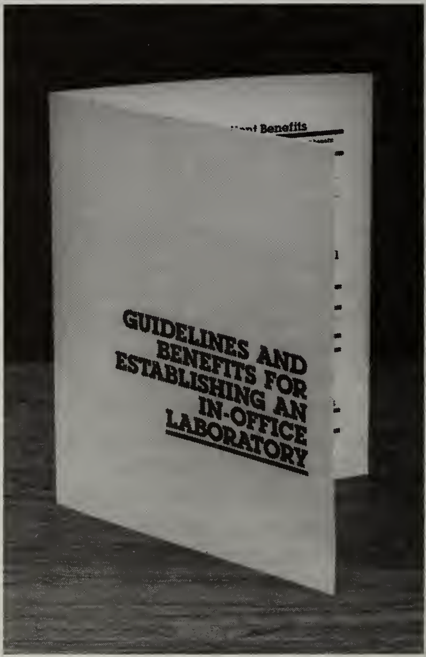
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Diagnostic Ultrasound Imaging in Pregnancy

NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

Introduction

From crude initial studies in the 1950s, ultrasonography in pregnancy has become a highly developed technology capable of detecting many fetal structural and functional abnormalities. It has found application in detecting ectopic pregnancy and multiple pregnancy, assessing fetal life and function, diagnosing physical anomalies, and guiding physicians as they make efforts to treat the fetal patient. The advent of ultrasound has overcome many of the diagnostic limitations of X-ray and has virtually eliminated the need for fetal exposure to ionizing radiation.

With these advantages and marked improvements in the technology and equipment, the use of ultrasound in obstetric practice has grown rapidly. The procedure is available in nearly all hospitals, and many physicians have acquired equipment for use in their offices. Further, because of the absence of clinically perceived risk of ultrasound and its usefulness in assessing structural anomalies, multiple pregnancy, and fetal size and gestational age, many practitioners have begun to advocate its routine use as a screening device in all pregnancies.

Lack of risk has been assumed because no adverse effects have been demonstrated clearly in humans. However, other evidence dictates that a hypothetical risk must be presumed with ultrasound. Likewise, the efficacy of many uses of ultrasound in improving the management and outcome of pregnancy also has been assumed rather than demonstrated, especially its value as a routine screening procedure.

The marked increase in the use of ultrasound, coupled with concerns regarding its safety and efficacy, prompted three NIH components—the National Institute of Child Health and Human Development (NICHD), the Office of Medical Applications of Research (OMAR), and the Division of Research Resources (DRR)—and the FDA National Center for Devices and Radiological Health to join in sponsoring a Consensus Development Conference to assess the use of diagnostic ultrasound imaging in pregnancy. The conference was held on February 6-8, 1984, after a year of preparation by the panel. After presenting a preliminary report at the conference, hearing the testimony of experts, and receiving comments and criticisms from the medical/scientific community, as well as from the public at large, the panel, consisting of physicians, basic scientists, epidemiologists, nurses, educators, sonographers, and public representatives, considered all of the information received and provided answers to the following questions that were posed to the panel:

1. What types of ultrasound scanning are currently used in obstetric practice? How extensive is this use? What is known about the dose/exposure to the fetus and the mother from each type?
2. For what purposes is ultrasound now used in pregnancy? For each use, what is the evidence that ultrasound improves patient management and/or outcome of pregnancy?

From the Office of Medical Application of Research, National Institutes of Health, Bethesda, Md.

Reprint requests to the Office of Medical Applications of Research, Room 216, National Institutes of Health, Bethesda, MD 20205 (Michael J. Bernstein).

3. What are the theoretical risks of ultrasound to the fetus and the mother? What evidence exists from animal, tissue culture, and human studies on the actual extent of the risk?
4. Based on the available evidence, what are the appropriate indications for, and limitations on, the use of ultrasound in obstretics today?
5. What further studies are needed of efficacy and safety of use of ultrasound in pregnancy?

1. What types of ultrasound scanning are currently used in obstetric practice? How extensive is this use? What is known about the dose/exposure to the fetus and the mother from each type?

On the basis of the collective experience of members of the panel, the material presented, and the literature review that was conducted, we conclude that in obstetric practice in the United States, use of diagnostic ultrasound imaging has an expanding role, and its use is becoming widespread. Information on the extent of use of diagnostic ultrasound in pregnancy was available from single institutions and states, marketing studies, the office survey conducted by the American College of Obstetricians and Gynecologists, and the 1980 National Natality Survey. These data lead to estimates of the percentage of pregnant women exposed to at least one ultrasound examination ranging from a low of 15 percent to a high of 40 percent. There is reason to believe that all of these data sources seriously underestimate the true extent of exposure to ultrasound since they do not necessarily include exposure via Doppler devices, including those used to listen to fetal heart tones and in antepartum and intrapartum fetal heart rate monitoring.

Exposure to imaging devices in the recent past has been to static scanners, real-time equipment of the linear array type, and mechanical sector scanners. The quantity used most often to report instrumentation output is intensity. Typical time average value ranges of intensity are 0.1-60mW/cm^2 (spatial average, temporal average intensity) and 1-200 mW/cm^2 (spatial peak, temporal average intensity). The spatial peak, pulse average intensity typically ranges from 1-200 W/cm^2 for such pulsed ultrasound equipment.

The time average intensities of the typical obstetrical Doppler devices used to listen to the fetal heart and for fetal heart rate monitoring in the antepartum and intrapartum period are within the same range as for pulsed equipment. These systems operate in the continuous wave mode, *viz,* 0.2-20mW/cm^2 (spatial average, temporal average intensity) and 0.6-80 mW/cm^2 (spatial peak, temporal average intensity). As new technologies and applications evolve, for example, measurement of blood flow using pulsed Doppler, exposure levels may be substantially higher.

Manufacturers of ultrasound equipment introduced into U.S. commerce are required to report outputs to the FDA. We recommend that these quantities be measured and reported to the user in a form consistent with the requirements of the AIUM/NEMA Safety Standard for Diagnostic Ultrasound Equipment.

Dose is a quantitative measure of an agent that is given or imparted and combines quantities such as intensity and exposure time. No dose quantity has been identified for ultrasound. Variation in tissue properties between individuals as well as scanning conditions influence dose in an unpredictable way. For all practical purposes, fetal dose cannot be quantitated precisely. For this reason, there are no data on the dose to either the mother or the fetus in the clinical setting. Documentation of dwell time and type of machine and transducer used would begin to address this problem. It is recommended that at least this specific exposure information be recorded for each examination. Thus, it is important that each exposure to ultrasound by all Doppler and imaging devices be recorded.

2. For what purposes is ultrasound now used in pregnancy? For each use, what is the evidence that ultrasound improves patient management and/or outcome of pregnancy?

Ultrasound has been used in a wide variety of clinical situations to aid in managing pregnancy. For each of these applications, there is literature recording the clinical experience from various centers, with evidence of benefits ultrasound has had in each respective application, although these applications have not been subjected to the rigorous evaluation provided by a randomized, controlled clinical trial. The following should not be considered circumstances in which use of diagnostic ultrasound imaging is mandatory. Rather, where significant clinical questions exist, the resolution of which would alter the remainder of prenatal care, ultrasound can be of benefit for:

- *Estimation of gestational age for patients with uncertain clinical dates, or verification of dates for patients who are to undergo scheduled elective repeat cesarean delivery, indicated induction of labor, or other elective termination of pregnancy.* Ultrasonographic confirmation of dating permits proper timing of cesarean delivery or labor induction to avoid premature delivery.
- *Evaluation of fetal growth* (e.g., when the patient has an identified etiology for uteroplacental insufficiency, such as severe pre-eclampsia, chronic hypertension, chronic renal disease, severe diabetes mellitus, or for other medical complications of pregnancy where fetal malnutrition, i.e., IUGR or macrosomia, is suspected). Following fetal growth permits assessment of the impact of a complicating condition on the fetus and guides pregnancy management.
- *Vaginal bleeding of undetermined etiology in pregnancy.* Ultrasound often allows determination of the source of bleeding and status of the fetus.

- *Determination of fetal presentation* when the presenting part cannot be adequately determined in labor or the fetal presentation is variable in late pregnancy. Accurate knowledge of presentation guides management of delivery.
- *Suspected multiple gestation* based upon detection of more than one fetal heartbeat pattern, or fundal height larger than expected for dates, and/or prior use of fertility drugs. Pregnancy management may be altered in multiple gestation.
- *Adjunct to amniocentesis.* Ultrasound permits guidance of the needle to avoid the placenta and fetus, to increase the chance of obtaining amniotic fluid, and to decrease the chance of fetal loss.
- *Significant uterine size/clinical dates discrepancy.* Ultrasound permits accurate dating and detection of such conditions as oligohydramnios and polyhydramnios, as well as multiple gestation, IUGR, and anomalies.
- *Pelvic mass detected clinically.* Ultrasound can detect the location and nature of the mass and aid in diagnosis.
- *Suspected hydatidiform mole* on the basis of clinical signs of hypertension, proteinuria, and/or the presence of ovarian cysts felt on pelvic examination or failure to detect fetal heart tones with a Doppler ultrasound device after 12 weeks. Ultrasound permits accurate diagnosis and differentiation of this neoplasm from fetal death.
- *Adjunct to cervical cerclage placement.* Ultrasound aids in timing and proper placement of the cerclage for patients with incompetent cervix.
- *Suspected ectopic pregnancy* or when pregnancy occurs after tuboplasty or prior ectopic gestation. Ultrasound is a valuable diagnostic aid for this complication.
- *Adjunct to special procedures,* such as fetoscopy, intrauterine transfusion, shunt placement, *in vitro* fertilization, embryo transfer, or chorionic villi sampling. Ultrasound aids instrument guidance that increases safety of these procedures.
- *Suspected fetal death.* Rapid diagnosis enhances optimal management.
- *Suspected uterine abnormality* (e.g., clinically significant leiomyomata, or congenital structural abnormalities, such as bicornuate uterus or uterus didelphys, etc.). Serial surveillance of fetal growth and state enhances fetal outcome.
- *Intrauterine contraceptive device localization.* Ultrasound guidance facilitates removal, reducing chances of IUD-related complications.
- *Ovarian follicle development surveillance.* This facilitates treatment of infertility.
- *Biophysical evaluation for fetal well-being* after 28 weeks of gestation. Assessment of amniotic fluid, fetal tone, body movements, breathing movements, and heart rate patterns assists in the management of high-risk pregnancies.
- *Observation of intrapartum events* (e.g., version/extraction of second twin, manual removal of placenta, etc.). These procedures may be done more safely with the visualization provided by ultrasound.
- *Suspected polyhydramnios or oligohydramnios.* Confirmation of the diagnosis is permitted, as well as identification of the cause of the condition in certain pregnancies.
- *Suspected abruptio placentae.* Confirmation of diagnosis and extent assists in clinical management.
- *Adjunct to external version from breech to vertex presentation.* The visualization provided by ultrasound facilitates performance of this procedure.
- *Estimation of fetal weight and/or presentation in premature rupture of membranes and/or premature labor.* Information provided by ultrasound guides management decisions on timing and method of delivery.
- *Abnormal serum alpha-fetoprotein value* for clinical gestational age when drawn. Ultrasound provides an accurate assessment of gestational age for the AFP comparison standard and indicates several conditions (e.g., twins, anencephaly) that may cause elevated AFP values.
- *Followup observation of identified fetal anomaly.* Ultrasound assessment of progression or lack of change assists in clinical decision-making.
- *Followup evaluation of placenta location for identified* placenta previa.
- *History of previous congenital anomaly.* Detection of recurrence may be permitted, or psychologic benefit to patients may result from reassurance of no recurrence.
- *Serial evaluation of fetal growth in multiple gestation.* Ultrasound permits recognition of discordant growth, guiding patient management and timing of delivery.
- *Evaluation of fetal condition in late registrants for prenatal care.* Accurate knowledge of gestational age assists in pregnancy management decisions for this group.

The information presented in the material reviewed by the panel, including the studies of Bennett, Eik-Nes, Bakketeig, Grennert, and others allowed no consensus that routine ultrasound examinations for all pregnancies improved perinatal outcome or decreased morbidity or mortality. There was, however, evidence that there was a higher rate of detection of twins and congenital malformations, as well as more accurate dating of pregnancy, but without significant evidence of improved outcome. The evidence with respect to the number of antepartum days of hospitalization and induction rates was contradictory among trials. The data on perinatal outcome were inconclusive. The panel recognized the inadequacy of the clinical trials on which these conclusions are drawn. Furthermore, it is acutely aware of the difficulty associated with conducting ideally controlled clinical trials and the large numbers of patients that must be included to uncover differences between control and experimental groups, where a morbid event occurs infrequently and spontaneously in the control population.

The panel concludes that diagnostic ultrasound for pregnant women improves patient management and pregnancy outcome where there is an accepted medical indication. Randomized, controlled clinical trials would be the best way in the United States to determine the efficacy of routine screening of all pregnancies.

3. What are the theoretical risks of ultrasound to the fetus and the mother? What evidence exists from animal, tissue culture, and human studies on the actual extent of the risk?

The panel conducted an extensive review of the primary literature on this subject and of reports by the Bureau of Radiological Health (1976), Food and Drug Administration (1982), World Health Organization (1982), and the National Council on Radiation Protection and Measurements (1984).

A number of epidemiological studies tend to support the safety of diagnostic ultrasound exposure in humans. In particular, in the three randomized clinical trials in which half of the women were exposed routinely to ultrasound, there was no association of routine ultrasound exposure with birth weight. In the two studies that addressed the subject, no association of ultrasound exposure with hearing loss was observed. On the other hand, many of the studies reporting on the safety of diagnostic ultrasound in humans were considered inadequate to address many other important issues because of technical problems in conducting such research.

Some of the more than 35 published animal studies suggest that *in utero* ultrasound exposure can affect prenatal growth. When teratological effects have been found, energies capable of causing significant hyperthermia have usually existed.

A number of biological effects have been observed following ultrasound exposure in various experimental systems. These include reduction in immune response, change in sister chromatid exchange frequencies, cell death, change in cell membrane functions, degradation of macromolecules, free radical formation, and reduced cell reproductive potential. It should be noted that (a) some of the studies employed energy levels greater than would be expected to exist in clinical use; (b) *in vitro* exposure conditions to ultrasound used in many of the experiments are hard to place in perspective for risk assessment; (c) some of the observations, for example, sister chromatid exchange frequency changes and induction of chromosomal abnormalities, have not been reproducible, tending to refute the original findings. Nevertheless, some of the reported effects cannot be ignored or overlooked and deserve further study as outlined in our answer to Question 5. The existence of these studies is one of the factors that contributed to our decision that routine ultrasound screening cannot be recommended at this time.

4. Based on the available evidence, what are the appropriate indications for, and the limitations on, use of ultrasound in obstetrics today?

From the body of information reviewed, taking into account the available bioeffects literature, data on clinical efficacy, and with concern for psychosocial, economic, and legal/ethical issues, it is the consensus of the panel that ultrasound examination in pregnancy should be performed for a specific medical indication. The data on clinical efficacy and safety do not allow a recommendation for routine screening at this time.

Ultrasound examinations performed solely to satisfy the family's desire to know the fetal sex, to view the fetus, or to obtain a picture of the fetus should be discouraged. In addition, visualization of the fetus solely for educational or commercial demonstrations without medical benefit to the patient should not be performed.

Prior to an ultrasound examination, patients should be informed of the clinical indication for ultrasound, specific benefit, potential risk, and alternatives, if any. In addition, the patient should be supplied with information about the exposure time and intensity, if requested. A written form may expedite this process in some cases. Patient access to educational materials regarding ultrasound is strongly encouraged. All settings in which these examinations are conducted should assure patients' dignity and privacy.

Given that the full potential of diagnostic ultrasound imaging is critically dependent on examiner training and experience, the panel recommends minimum training requirements and uniform credentialing for all physicians and sonographers performing ultrasound examinations. All health care providers who use this modality should demonstrate adequate knowledge of the basic physical principles of ultrasound, equipment, recordkeeping requirements, indications and safety.

5. What further studies are needed of efficacy and safety of use of ultrasound in pregnancy?

It is critical, in view of the existing data and the special considerations affecting fetal and embryonic development, to encourage and support a sustained research effort aimed specifically at test systems that can help provide a better data base for developing reasonable estimates of bioeffects and of risk. In particular, we recommend:

1. The study of fundamental mechanisms leading to bioeffects.
2. Laboratory experiments that focus especially on those

cellular processes that are most likely to be affected during embryonic and fetal development.

3. Postnatal studies in animals after *in utero* exposure to ultrasound.
4. Exploration of interactions between administered ultrasound and such developmentally significant agents as drugs, nutrition, ionizing radiation, hyperthermia, and hypoxia.
5. Development of improved dosimetry.

A long-term followup of infants involved in a randomized clinical trial would help clarify questions about the effect of ultrasound on development in humans, and other epidemiologic studies using a wide variety of methods should be considered. Studies of the psychosocial, ethical, and legal aspects of ultrasound use are also needed.

Further nonexperimental studies that seek to establish the clinical efficacy of ultrasound should address the question of its contribution to reducing morbidity and mortality. Randomized, controlled clinical trials of routine ultrasound screening in pregnancy should be conducted in the United States.

SPECIAL NOTICE

ANNOUNCING AN NIH CONSENSUS DEVELOPMENT CONFERENCE: LOWERING BLOOD CHOLESTEROL TO PREVENT HEART DISEASE

December 10-12, 1984

Masur Auditorium
Warren Grant Magnuson Clinical Center
National Institutes of Health
Bethesda, Maryland

Sponsored by the National Heart, Lung, and Blood Institute and the NIH Office of Medical Applications of Research

A Consensus Development Conference on the Lowering of Blood Cholesterol to Prevent Heart Disease will be held at the National Institutes of Health (NIH), December 10-12, 1984.

Elevated blood cholesterol is one of the major risk factors for the development of coronary heart.disease. The recently concluded Lipid Research Clinics Coronary Primary Prevention Trial demonstrated that reducing blood cholesterol levels reduced the risk of developing coronary heart disease.

This consensus conference will bring together researchers, medical specialists, clinicians, and representatives of other interested groups. Following two days of presentations by medical experts and discussion by the audience, a Consensus Panel will weigh the scientific evidence and formulate a draft statement in response to a number of key questions:

- Is the relationship between blood cholesterol levels and coronary heart disease causal?
- Will reduction of cholesterol levels prevent coronary heart disease?
- At what level of blood cholesterol should treatment be started and what is appropriate treatment?
- Should the population at large attempt to reduce their cholesterol levels?
- What are appropriate directions for research to explore?

On the final day of the meeting, the Consensus Panel Chairman will read the draft statement before the conference audience and invite comments and questions.

To register to attend this conference contact:

Ms. Peggy Connolly
Prospect Associates
Suite 401, 2115 East Jefferson Street
Rockville, Maryland 20852
(301) 468-6555

The Conference was sponsored by the following: National Institute of Child Health and Human Development, Mortimer B. Lipsett, M.D., Director; Office of Medical Applications of Research, NIH, J. Richard Crout, M.D., Director; Division of Research Resources, NIH, Betty H. Pickett, Ph.D., Director; National Center for Devices and Radiological Health, FDA, John Villforth, Director.

Members of the Consensus Development Panel were: Fredric Frigoletto, M.D., (Chairman), Chief, Maternal Fetal Medicine, Department of Obstetrics and Gynecology, Brigham and Women's Hospital, Professor of Obstetrics and Gynecology, Harvard Medical School, Boston, Massachusetts; Robert Auerbach, Ph.D., Professor of Zoology, University of Wisconsin, Madison, Wisconsin; Alexander Brickler, M.D., Family Practitioner, Obstetrics and Gynecology, Tallahassee, Florida; Kenneth R. Gottesfeld, M.D., Clinical Professor of Obstetrics, Gynecology, and Radiology, University of Colorado Health Sciences Center, Rose Medical Center, Denver, Colorado; Charles Hohler, M.D., Director of Perinatology and Perinatal Ultrasound, Division of Reproductive Medicine, St. Joseph's Hospital and Medical Center, Phoenix, Arizona; Michael L. Johnson, M.D., Director, Division of Diagnostic Ultrasound, Associate Professor of Medicine and Radiology, University of Colorado Health Sciences Center, Denver, Colorado; Jean H. Lea, M.P.H., R.D.M.S., Associate Professor, College of Allied Health, University of Oklahoma, Oklahoma City, Oklahoma; Rosanna L. Lenker, B.S.N., C.N.M., C.F.N.P., Instructor, Department of Obstetrics and Gynecology, Pennsylvania State University School of Medicine, Milton S. Hershey Medical Center, Hershey, Pennsylvania; George A. Little, M.D., Professor and Chairman, Department of Maternal and Child Health, Dartmouth Medical School, Hanover, New Hampshire; William D. O'Brien, Jr., Ph.D., Professor of Electrical Engineering and of Bioengineering, Bioacoustics Research Laboratory, University of Illinois, Urbana, Illinois; Diana Petitti, M.D., Assistant Professor, Division of Family and Community Medicine, University of California at San Francisco School of Medicine, San Francisco, California; John T. Queenan, M.D., Professor and Chairman, Department of Obstetrics and Gynecology, Georgetown University School of Medicine, Washington, D.C.; Karen Rothenberg, M.P.A., J.D., Assistant Professor, University of Maryland School of Law, Baltimore, Maryland; Thomas H. Shepard, M.D., Professor of Pediatrics, Head, Central Laboratory for Human Embryology, Department of Pediatrics, University of Washington, Seattle, Washington.

Members of the Planning Committee were: Mortimer B. Lipsett, M.D., (Chairman), Director, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland; Duane Alexander, M.D., Deputy Director, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland; James Benson, Deputy Director, National Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Maryland; Heinz Berendes, M.D., Director, Epidemiology and Biometry Research Program, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland; Fredric Frigoletto, M.D., Chief, Maternal Fetal Medicine, Department of Obstetrics and Gynecology, Brigham and Women's Hospital, Professor of Obstetrics and Gynecology, Harvard Medical School, Boston, Massachusetts; James G. Hill, Chief, Office of Planning and Evaluation, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland; Itzhak Jacoby, Ph.D., Deputy Director, Office of Medical Applications of Research, National Institutes of Health, Bethesda, Maryland; Anne Krey, Genetics and Teratology Section, Center for Research for Mothers and Children, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland; Stephen W. Smith, Ph.D., Deputy Chief, Acoustics Branch, National Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Maryland; Melvin E. Stratmeyer, Ph.D., Chief, Acoustic Radiation Branch, Division of Risk Assessment, Office of Radiological Health, National Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Maryland.

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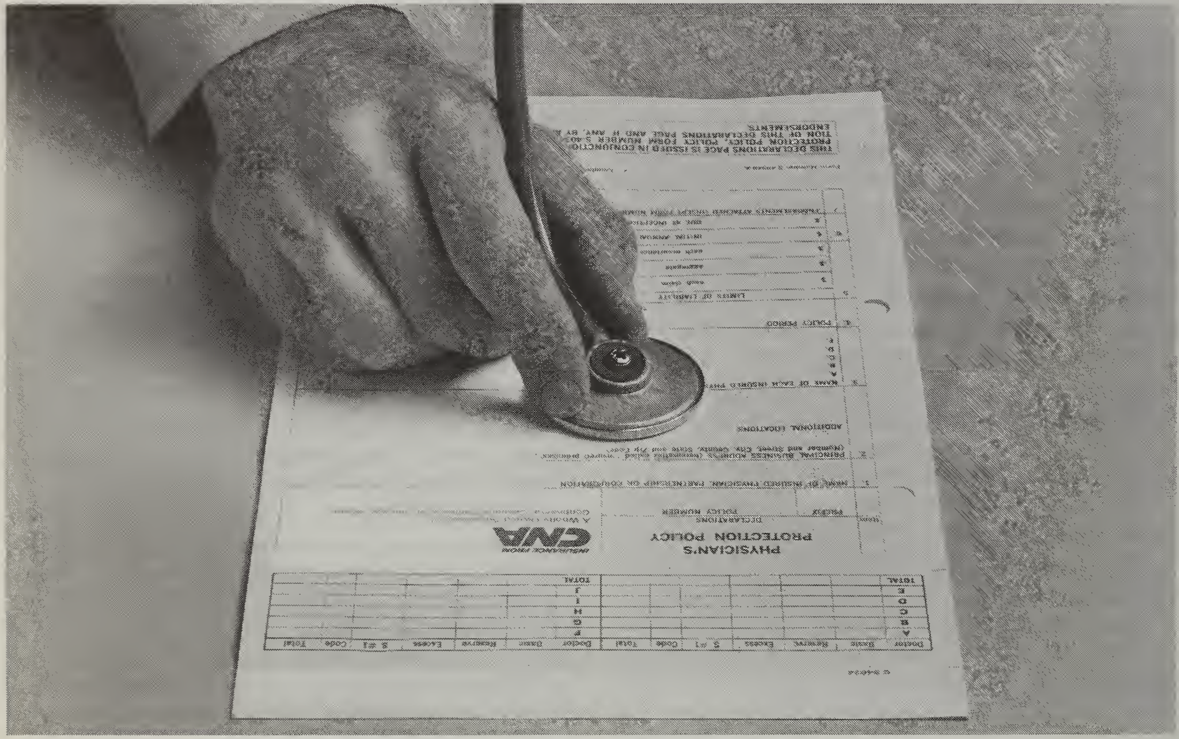

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The Origins of Anesthesia: Part III

SHERWIN B. NULAND, M.D.

SUSPENDED ANIMATION

Until the past few decades, medical research has been viewed by the general public as being pragmatic, or, in the present parlance, problem-oriented. Supposedly, a clinician identifies a need at the bedside, takes it to the laboratory, and emerges months or years later with a solution, which he then applies to his patients. Although there are certainly some outstanding examples of major contributions that have made in this way, the more usual course of events is now quite different: a skilled laboratory investigator, who may or may not be clinically oriented, applies the methods of basic science in order to learn more about some natural phenomenon in which he has become interested in the course of his research. Often, the new medical discovery which results is simply the next logical step in the direct sequence of an investigator's resolution of some theoretical problem, or it may even be the serendipitous outcome of otherwise abstract studies. It then leaves the vacuum flasks and the centrifuges to undergo clinical trials in sick people. The romantic image of the bedside clinician periodically disappearing into the laboratory has become less and less a possibility—research technology evolved so rapidly in its complexities that we seem at present to have reached a state of affairs in which the basic or pre-clinical scientists determine by their investigations (and perhaps by their influence with funding agencies), the direction that clinical medicine will take—the tail has become the dog, and that too is a miracle which, for better or worse, has been wrought by medical science.

Even painless surgery, a clinical need if ever there was one, came about because studies by basic scientists identifying the properties of certain gases had prepared the armamentarium, awaiting only a keen clinical imagination to apply it to an obvious problem. But of the several blind alleys that went off the main track of the anesthesia evolution, there is one that is characterized by the old romantic image: a doctor, in this case a general practitioner in a Shropshire village in 1823, set out to relieve the agony caused by the amputations, extractions and lancings that were so commonly required during the course of his country practice. As he wrote:

> *There is not an individual who does not shudder at the idea of an operation, however skillful the surgeon or urgent the case, knowing the great pain that the patient must endure, and I have frequently lamented, when performing my own duties as a surgeon that something has not been thought of whereby the fears may be tranquilized and suffering relieved.*

This village practitioner conceived the idea of creating a state of what he called "suspended animation" in his patients, hoping to induce this by the use of an inhaled gas which might pass into the bloodstream and obtund the nervous system. The young physician bought equipment, set up a home laboratory, did a series of animal experiments, and by 1824 published a communication, the title of which described his work and its intention: *A Letter on Suspended Animation Containing Experiments Showing that it may be Safely Employed during Operations on Animals, with the View of Ascertaining its Probable Utility in Surgical Operations on the Human Subject.* The author of this remarkable letter was Henry Hill Hickman; he was 24 years old.

The gas that Hickman employed was carbon dioxide; his technique actually induced a controlled CO_2 narcosis, which was very effective in providing the desired outcome. Although carbon dioxide has never proven to be a practical means of general anesthesia, there is no doubt that the originator of the principle of inhaling a gas to produce surgical anesthesia was Henry Hill Hickman, the rural general practitioner.

The open *Letter* was addressed to Thomas Andrew Knight, who had achieved Fellowship in the Royal Society in recognition of his contributions to horticulture. Horticulture may seem an inappropriate credential upon which to base a choice of potential sponsor for a method of anesthesia, but Hickman did not have Knight's professional background in mind. What he did have in mind was the fact that Knight and Humphrey Davy, by now a lofty and socially remote baronet, were good friends, and that Sir Humphrey was, in fact, the President of the Royal Society. With Davy's support, Hickman felt sure that his methods would be tried by some of the leaders of British medicine, first to confirm his results experimentally and then to take the great next step to human surgery, a step that Hickman himself did not feel qualified by position or medical experience to essay.

This hope was frustrated by Knight's apparent indifference to the whole idea, and there is no evidence that

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SHERWIN B. NULAND, M.D., Associate Clinical Professor of Surgery, Yale University School of Medicine. Dr. Nuland is Literary Editor of *Connecticut Medicine.* This is Chapter V and VI of Dr. Nuland's book *The Origins of Anesthesia.*

he made any attempt to interest Davy or any other Fellows in the investigation of the use of carbon dioxide anesthesia.

After 3 years of fruitlessly waiting for some response, Hickman went to Paris, to put his case before what was then the most advanced scientific community in the world. Again seeking a lofty patron, he wrote to King Charles X, who sent his letter on to the Académie Royale de Médicine. The Académie treated him somewhat more kindly than had his own countrymen, going so far as the appointment of a 5-member committee to study his claims. Baron Dominique Jean Larrey (1766-1842), who had been the much-revered senior surgeon of Napoleon's army, was the only committee member to see merit in Hickman's proposals. Larrey was outvoted, and the matter was dropped. Hickman went home a disappointed man, broken in spirit. He died less than 2 years later, his being the first of a series of tragic deaths involving the pioneers of anesthesia. His fate was an obscurity so profound that his name does not even appear in the endlessly-long biographical index of Fielding Garrison's monumental reference tome, *An Introduction to the History of Medicine.*

However, the memory of Hickman was not to disappear forever. In 1930, the year following the final edition of Garrison's classic, a Hickman Centenary Exhibition was held at the Wellcome Historical Medical Museum in London, occasioned by the fact that Sir Henry Wellcome, the Museum's founder, had become fascinated with the life of that unheeded prophet. A tablet was placed in Bromfield Church, where Hickman had been baptized and in whose cemetery he is buried. There is no reason to disagree with the statement which appears on that memorial stone:

> *This tablet is placed here at the initiative of the Section of Anesthetics of the Royal Society of Medicine as a centenary tribute to the memory of the earliest known pioneer of anesthesia by inhalation. A.D. 1930.*

CRAWFORD LONG OF GEORGIA

> *While it does not appear to us that the discovery or, as some prefer to say, the invention, of surgical anesthesia required any remarkable intellectual endowments or high scientific training, and it cannot be said that Long, Wells or Morton were possessed of these, it was the outcome of the spirit of inquiry, of keen observation, of boldness, of perserverance, of resourcefulness, of a search for means to improve a useful art, of interest in the practical rather than the theoretical, —all traits more or less characteristic of the American mind, and I do not think that it was wholly an accident that our country should have given birth to the art of painless surgery. I find evidence of this view in the fact that not one but several Americans were working independently upon the same problem and that the solution of the problem is an exclusive achievement of our countrymen.*
>
> *William Henry Welch*
> *Ether-Day Address*
> *Massachusetts General Hospital*
> *October 16, 1908*

Few would disagree that surgical anesthesia is the greatest gift that American medical science has given to the world. None of the great advances that have been made in our country during the 20th century eclipse the contributions of a small group of Americans almost 150 years ago. Having traced the background and discovery that led to those contributions, the narrative now crosses the Atlantic to a small town in rural Georgia, and picks up the story of yet another tangent along which moved another country doctor.

There is a certain eminent appropriateness in the fact that the professional training of Crawford Williamson Long (1815-1878) is an epitome of the state of medical education as it existed in the more southern and western states of our country in the middle third of the 19th century. In 1835, Long graduated from Franklin College, now the University of Georgia, which had been chartered in Athens 50 years earlier. He taught school for a year in his home town of Danielsville, and then apprenticed himself for a few months to Dr. George R. Grant, in the town of Jefferson.

Although Long's period as a preceptee may have had its rewards, it was more likely to have been as described by Daniel Drake, the great physician of the Mississippi Valley area, writing in 1832 about the apprenticeship system: "The physicians of the United States, are culpably inattentive to the studies of their pupils, and . . . this is one of the causes which retard the improvement, and arrest the elevation of the profession. Exceptions . . . are frequently met with, especially in the great cities; but they are still *only* exceptions."

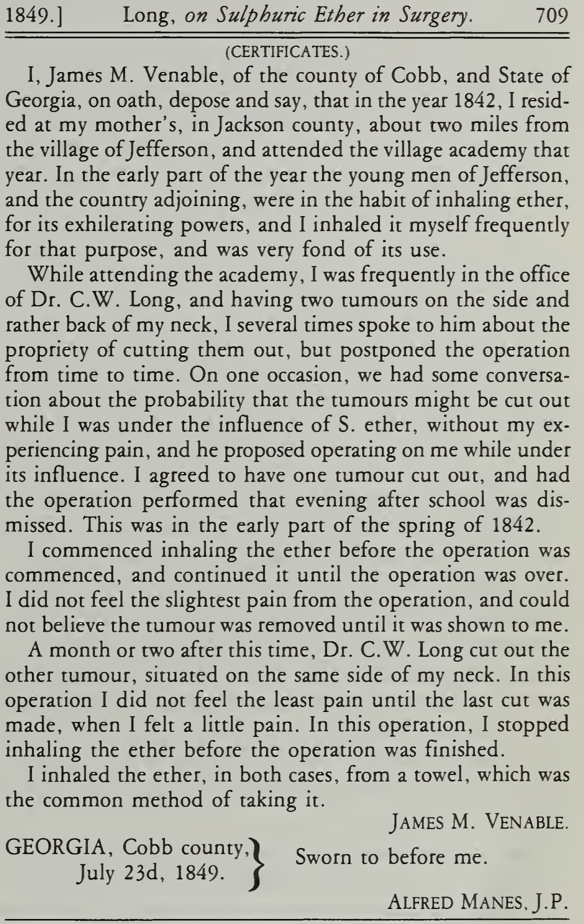
Whatever may have been the quality of his brief experience with Dr. Grant, Long realized his need for more formal medical education, and set off on horseback to get it. His journey took him across the mountains of western North Carolina and eastern Tennessee, through forest lands that harbored not only isolated communities of backwoods settlers but the sometimes hostile Indian tribes that still lived in those areas. Finally, after several weeks, he arrived at Lexington, Kentucky, where he enrolled at the Medical Department of Transylvania University, at that time in the 36th year of its existence and thriving, with a roster of 262 students. But even the foremost medical school in the South did not meet Long's requirements for a more scientific training, and he traveled north to enter the University of Pennsylvania in 1838, America's oldest medical school, where the country's finest faculty had been assembled. According to a biography written in 1928 by Long's daughter, Frances Long Taylor, it was during his student days in Philadelphia that her father first became acquainted with ether frolics and laughing gas parties, having been introduced to the diverting effects of those 2 gases not in the classroom, but by itinerant showmen who gave public lectures on chemistry. In writing this, she was underestimating the extent of her father's more formal knowledge of contemporary chemistry. Under the influence of Benjamin Rush, several members of the medical school faculty had done work with pneumatic medicine, lecturing and writing about the properties of both nitrous oxide and ether. Nathaniel Chapman, Long's Professor of the Theory and Practice of Physic, had, in fact, written what is probably the best description extant of the preanesthetic clinical uses of ether, in his *Elements of Therapeutics and Material Medica,* published in 1831.

After receiving his degree in 1839, the young physician "walked the wards" for 18 months in New York, as so many of his Northern colleagues had done in the great teaching hospitals of England and France. There were few Southern physicians as well prepared for the highest quality of clinical work as was Crawford Long, and the temptation to return to Philadelphia to practice was great. But loyalty to his father brought Long back to Jefferson, Georgia, where he bought the practice of his old preceptor, George Grant, in 1841. He was 25 years of age.

The course of Crawford Long's medical training has been reviewed not only because it characterized the type of educational pathway that was taken by American physicians of his day, but also to point out that the great majority of practitioners departed from that track at any of several steps along the way, most commonly before actually obtaining the M.D. degree. What we see in the education of Long is the best that the young country had to offer. He was not, as he has so often been characterized, a rural bumpkin of a doctor who chanced to use ether one day, but rather a highly trained physician with a strong background in clinical medicine and in the experimental methods of science. He was well prepared by education and by his own scientific inclinations to test his hunches by clinical trial. Even the intellectually redoubtable William Henry Welch seems not to have appreciated the quality of Long's exposure to contempory science.

The able and personable young physician soon became a popular figure in the community surrounding Jefferson. He acquired a circle of friends who brought to the area what they could of a worldly interest in things novel and intellectually adventurous. Not surprisingly, they became interested first in laughing gas, and then in ether. On several occasions during which Long and his friends used ether, he was able to make the same observation as had Faraday and Davy, namely that those who inhaled enough of the vapor "did not feel the least pain" when being struck a blow or falling down. There is no better example to be found of Pasteur's maxim, "where observation is concerned, chance favors only the prepared mind," than the use to which this highly-trained physician put his experience.

Unfortunately, Long did not publish his report until 1849, 3 years after hearing of William Morton's triumph. Even then, there was a characteristic reticence in his presentation, including the fact that he did not publish until he had first traveled to the Medical College of Georgia in Augusta to describe before that faculty his experience with ether seven years earlier. (See Figure 1).



1849.] Long, *on Sulphuric Ether in Surgery.* 709

(CERTIFICATES.)

I, James M. Venable, of the county of Cobb, and State of Georgia, on oath, depose and say, that in the year 1842, I resided at my mother's, in Jackson county, about two miles from the village of Jefferson, and attended the village academy that year. In the early part of the year the young men of Jefferson, and the country adjoining, were in the habit of inhaling ether, for its exhilerating powers, and I inhaled it myself frequently for that purpose, and was very fond of its use.

While attending the academy, I was frequently in the office of Dr. C.W. Long, and having two tumours on the side and rather back of my neck, I several times spoke to him about the propriety of cutting them out, but postponed the operation from time to time. On one occasion, we had some conversation about the probability that the tumours might be cut out while I was under the influence of S. ether, without my experiencing pain, and he proposed operating on me while under its influence. I agreed to have one tumour cut out, and had the operation performed that evening after school was dismissed. This was in the early part of the spring of 1842.

I commenced inhaling the ether before the operation was commenced, and continued it until the operation was over. I did not feel the slightest pain from the operation, and could not believe the tumour was removed until it was shown to me.

A month or two after this time, Dr. C.W. Long cut out the other tumour, situated on the same side of my neck. In this operation I did not feel the least pain until the last cut was made, when I felt a little pain. In this operation, I stopped inhaling the ether before the operation was finished.

I inhaled the ether, in both cases, from a towel, which was the common method of taking it.

JAMES M. VENABLE.

GEORGIA, Cobb county,
July 23d, 1849. } Sworn to before me.

ALFRED MANES, J.P.

Figure 1
Affidavit of James Venable, describing the first use of ether anesthesia, on March 30, 1842.

By the time of publication, the battle for priority, which will be described more fully in subsequent chapters, had been raging for almost 3 years between the advocates of Horace Wells, of William Morton, and of Charles Jackson. It was not a battle that was willingly joined by Long. Only because of the urging of friends, he wrote to Senator William Crosby Dawson and to his Congressman, Junius Hillyer, describing the work that he had done. Dawson, intent upon investigating Long's claim, chose an unlikely agent to do it for him, the chemist from Boston, Charles T. Jackson, himself already deeply immersed in the battle.

Jackson arrived in Athens, Georgia, on March 8, 1854, where Long had been practicing for the past 4 years. Their meeting was kept from being a confrontation by the open graciousness of Long and the surprisingly unbiased objectivity of Jackson. For some time there had been more than honor at stake, as Congress was preparing to decide upon a bill awarding a purse of $100,000 to whomever was granted the distinction of priority. As a result of studying his competitor's documents, Jackson was convinced of the events of March, 1842. There is evidence that he proposed to Long that the two of them prepare a joint claim to Congress, with Jackson being given credit for the discovery and Long for the first clinical use, thereby effectively shutting out Wells and that bête noire of Jackson's, William Morton. Long saw no reason to share anything, not because he was stubborn or greedy, but because he felt the certainty of being right.

Jackson, whatever else may be said of him, was too honest, at least in this case, to falsify his report to Dawson. Of course, his honesty was encouraged by his hatred of Morton, described in a later chapter. On April 5, 1854, when the Senate was making its final judgment on the bill (S.B. 210), Senator Dawson announced that he had a letter from Dr. Jackson acknowledging that the unfamiliar name of Dr. Crawford Williamson Long of Georgia was the one to which should be assigned the honor of having been the first to use ether. Since the bill specified that the award was to be given either to Morton, Jackson or the representative of Wells, whichever was judged most fitting by the Secretary of the Treasury, the introduction of Long's name threw the entire proceeding into a turmoil, from which it never recovered. The bill, although passed by the Senate and sent to the House of Representatives, was not signed by the President. The congressional battle was over. William Morton turned to the civil courts to try to prove his case for claiming a valid patent, but Long was not to be involved beyond this point.

The infighting over the monetary award is described more fully in the sections of this book involving Morton and Jackson, but one further word must be said about Crawford Long's interest in it. It is the contention of his daughter that her father's intention in becoming involved in the legislative showdown was in "preventing another from being recognized by Congress as the discoverer, and not wishing any pecuniary reward himself." Her statement is supported not only by the fact that Long, even with Jackson's letter of admission, never promoted the matter of a prize again, but also by everything that is known about Long's diffident and honorable character.

Jackson, whatever may have been his more honorable motives, sought an opportunity to support his own claim, subtly and with a certain artful statesmanship. He makes of his apparent adversary a staunch ally by saying, "when he saw my dates he perceived that I made the dicovery before him, and he did not suppose that anything done after that would be considered of much importance"—a boost for Jackson, a blow against Morton, and an ingratiating pat on the back to the admirable but non-threatening Long.

None of the four contenders for the crown of discovery had an easy life after the controversies began, but at least Long's, although arduous and toilsome, was not tragic. He was the only one of the four who was not destroyed by his involvement in the anesthesia dispute. In fact, his contributing role was rediscovered by J. Marion Sims in 1877, who went so far as to write a thoroughgoing discussion of Long's originality in the *Virginia Medical Monthly.* The article gave considerable emotional sustenance to the aging Long, now beaten down with the burdens of caring for a large group of indigent patients in an area that had been impoverished by the ravages brought by the Civil War and a long Yankee occupation.

Even Crawford Long's moment of death involved ether anesthesia and his own self-negation. On June 16, 1878, the 62-year-old country practitioner had just completed the delivery of a child from an etherized mother, when he felt a wave of unconsciousness coming over him. Just before being enveloped in darkness he managed to pass the infant into the arms of an attendant, with the admonition, "Care for the mother and the child first." He fell across the patient's bed, and a few hours later the first man to use ether surgical anesthesia was dead of a massive stroke.

Over the next few decades, posthumous recognition came in the form of statues, plaques, portraits, and oratorical tributes. The most recognized and widely seen of the memorials stands in the Statuary Hall of the United States Capitol. Long and his Franklin College roommate, Alexander Stephens (who had gone on to become one of the South's most brilliant political figures) were chosen by the state legislature to be the two honored sons whose statues would represent the highest accomplishments of Georgia.

The contribution of Crawford Williamson Long has been described in the first paragraph of this chapter as a tangent to the main line of the narrative, and a tangent it was, in spite of its originality. For, unlike the influence that Morton had, no one was ever emboldened to give surgical anesthesia because Long used it; medical science never learned from him that surgical anesthesia was possible—all of this had to await William Thomas Green Morton and that autumn morning in Boston. Welch, after all, has the last word:

> *Long is necessarily deprived of the larger honor which would have been his due had he not delayed publication of experiments with ether until several years after the universal acceptance of general anesthesia. . . . We need not withhold from Dr. Long the credit of independent and prior experiment and discovery, but we cannot assign to him any influence upon the historical development of our knowledge of surgical anesthesia or any share in its introduction to the world at large.*

Month in Washington

Administration Revives 'Baby Doe' Suit

The Reagan Administration announced in July that it filed an appeal to a court ruling that struck down the federal "Baby Doe" regulation.

In May, the US District Court for the Southern District of New York invalidated the regulation, affirming that the government does not belong in cases involving the medical treatment of severely handicapped newborns.

The AMA had joined forces with other medical and hospital organizations in filing suit against the regulation, maintaining that medical decisions should be the responsibility of parents in consultation with physicians and others.

A tersely worded statement released by the White House Deputy Press Secretary Marlin Fitzwater said: "HHS has carried out its responsibility to investigate Infant Doe cases to the fullest extent of its legal authority. HHS efforts have been thwarted by court decisions invalidating Infant Doe regulations and a court injunction last month has prevented further Infant Doe investigations or other enforcement actions for the present."

"That decision is being appealed. HHS will continue to fully carry out its responsibilities to protect all infants to the fullest extent of its legal authority."

* * * *

Senate Votes Unanimously on 'Baby Doe'

The Senate voted 89 to 0 to require treatment of handicapped infants when, in the doctor's judgment, treatment would correct or ameliorate the infant's condition.

The Senate's "Baby Doe" bill was passed and sent along with the House-approved version to members of a House-Senate conference committee on July 27.

Treatment guidelines, the centerpiece of the bill, say that care should be withheld only when:

- the infant is chronically and irreversibly comatose,
- treatment would not correct all of the infant's life-threatening conditions,
- treatment would merely prolong dying, or
- treatment would be futile and inhumane.

Thus, it does not require unending treatment when an infant is doomed to die, regardless of medical efforts. Nor does is require that physicians perform surgery for correctable defects when another defect is lethal and untreatable. It also gives the physician the freedom, say the bill's sponsors, to make a "judgment call" when the child has little chance for survival.

However, it requires physicians to treat correctable defects, without regard for the child's other handicaps.

The AMA resisted passage of the bill, saying it would require states "to intervene and second-guess the individual medical decisions made by parents, in consultation with physicians." Said AMA Vice President James H. Sammons, M.D.: "The AMA is dismayed by the Senate's approval of language relating to medical care of severely ill infants, and will continue to make our concerns known as the bill goes to conference committee."

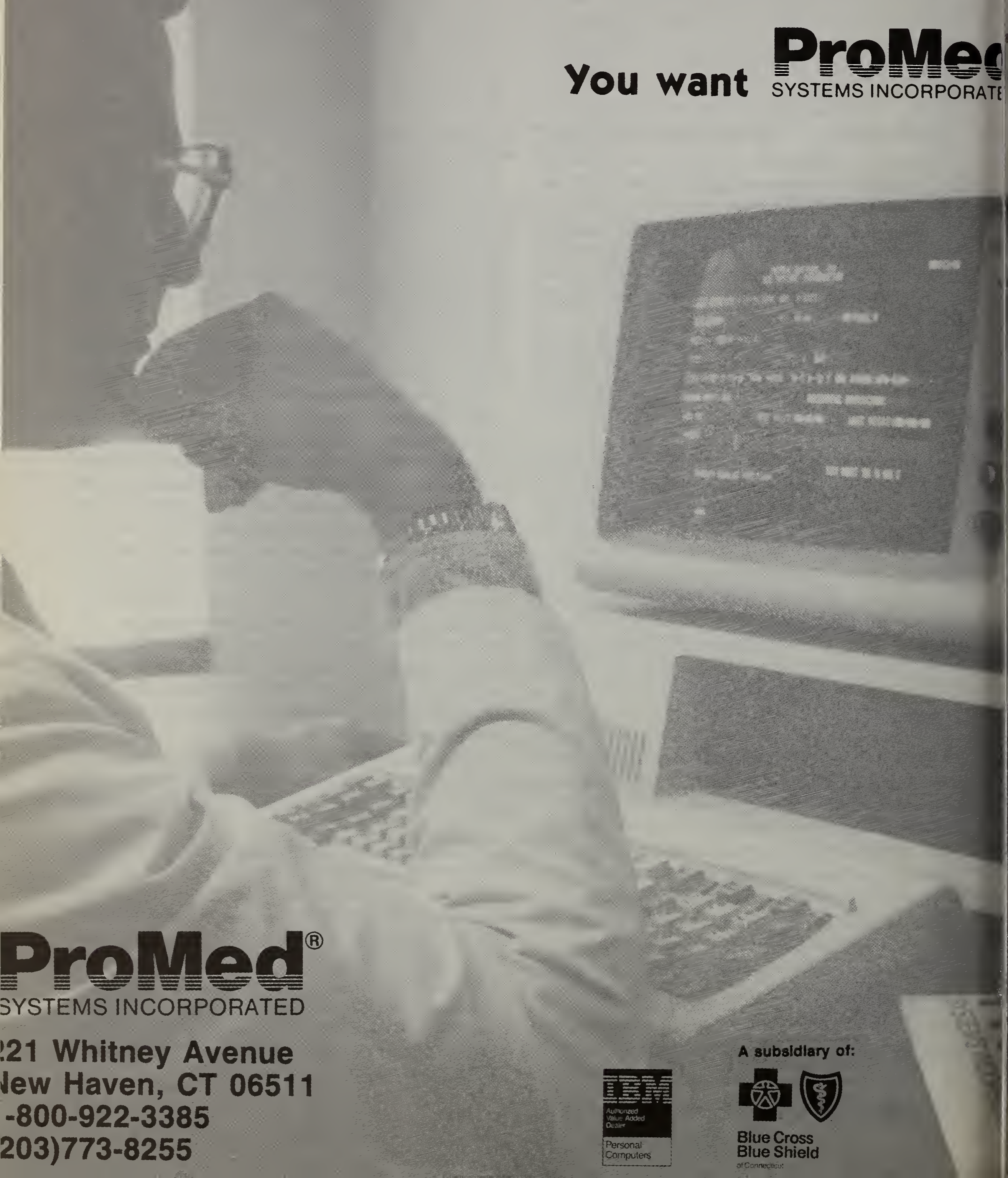
AMA President Joseph F. Boyle, M.D., does not rule out the possibility of an AMA lawsuit once the bill passes Congress. "We will have to assess very carefully the legal climate," he said. It would appear that this bill might be subject to the same kind of Constitutional challenges as were the HHS regulations that were adopted (and were struck down by a New York district court judge).

"In the interests of individuals, and the freedom of parents to make decisions on behalf of their own children, it may well be that there will be a (legal) course of action," Dr. Boyle said.

Pediatric, obstetric and hospital groups endorsed the bill, believing that their support would avert a wide-open debate on the floor of the Senate. By refusing to negotiate on "compromise" language contained in the bill, they feared that more restrictive Baby Doe provisions would be proposed.

Because the bill contains no provisions to withhold "inhumane or unconscionable" treatment, the bill puts physicians "in the intolerable position of continuing to provide services that will provide only intense suffering," said Dr. Boyle.

Prepared by the Washington, D.C.
Office of the American Medical Association



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The state, not federal, government would be responsible for ensuring that an infant is treated and fed. According to the bill, states would be required to set up a system of hospital representatives to report instances of medical neglect. States that fail to comply would lose part of their anti-child abuse funds.

* * * *

Nationwide Physician Fee Freeze Implemented by the Government

A deficit reduction measure that includes a rigidly-monitored 15-month freeze on physicians' Medicare fees has been signed by President Reagan, and HCFA officials are now grappling with details of its implementation.

The measure provides financial and administrative incentives for "participating physicians" who accept assignment on all Medicare claims and authorizes fines of up to $2,000 or a suspension from Medicare for up to five years on "nonparticipating physicians" found to have a pattern of increasing charges to Medicare patients during the freeze.

Now estimated to save $2.5 billion over three years, the physician fee freeze is a substantial portion of the $6.5 billion in Medicare reductions contained in the larger budget measure, called the Deficit Reduction Act of 1984 (HR 4170) and approved by Congress in late June. Other major Medicare savings come from limits on hospital reimbursement, increased Medicare premiums, and fee schedules for clinical lab services.

The freeze, in its monitoring provisions, goes beyond language adopted by either the House or the Senate in earlier deliberations on various budget bills that were tied into HR 4170. The monitoring plan was designed by House conferees with input from the White House Office of Management and Budget.

The freeze is retroactive to July 1, 1984 and will run until October 1, 1985. Fee screens will be updated each October 1. The data on which fee adjustments are based will also be moved forward by three months so as not to further increase the current 18 month "lag" on the economic index, however.

A "participating physician" concept similar to that employed by some Blue Shield plans will be set up for physicians who choose during an annual election period to take all Medicare claims on assignment, thereby agreeing to accept the Medicare allowance as full reimbursement and to bill the patient for the 20% of the allowance not covered by Medicare.

As an inducement for "participating," these physicians will be permitted during the freeze to bill Medicare their customary charges. Although their fees will remain frozen, increases in the billed charges will be considered in updating the customary charge profiles of "participating physicians" at the end of the freeze. The economic index that limits increases in prevailing charges will still apply, however.

Other incentives for "participating physicians," include listing in directories and toll-free hotlines identifying "participating physicians"; electronic billing of claims (where Medicare carriers have the capability); and permission to bill the Medicap insurer the full amount allowed by Medicare leaving the insurer to collect from Medicare.

"Nonparticipating physicians" may continue to assign Medicare claims on a case by case basis. They will, however, be monitored periodically to compare their most recent Medicare charges with their charges in the three-month period immediately following the American Medical Association's call for a voluntary freeze (April 1 to June 30, 1984). No charges in excess of those charged during the base period will be recognized when "customary charge profiles" are updated at the end of the freeze.

In addition, if the monitoring uncovers a pattern of increased fees to Medicare patients or an unusual volume of expenditures per capita the physician can, depending on a showing of intent, be fined up to $2,000 or "debarred" from the Medicare program for up to five years. The fines may be used, in some cases, to repay beneficiaries the physician "overcharged."

Any physician who is the "sole community physician" or the "sole source of essential specialized services in a community" could be fined but not removed from the program.

Many of the details of the monitoring provisions and the "participating physician" plan were left to the discretion of the Department of Health and Human Services.

* * * *

Disability Criteria to be Updated

As part of an ongoing effort to involve medical experts more directly in the determination of disability eligibility criteria, the Social Security Administration in July held the first of what is expected to be a series of conferences on various conditions suffered by significant numbers of disability beneficiaries.

Co-sponsored by the American Medical Association, the first conference held in Washington, on cardiovascular impairment, and was intended to serve as a model for others to follow. It involved SSA officials, outside experts and representatives of beneficiaries, employers and insurers. The intent was to look at the impact of new technology and medical treatment on patients with cardiovascular impairments and how those changes might change criteria for eligibility.

The conferences follow widespread criticism of SSA's earlier attempts to implement a 1980 law calling for periodic reviews of disability beneficiaries. The reviews, which led to the cut off of disability benefits for many mentally impaired individuals, resulted in a number of court cases and congressional efforts to modify the review process.

The major criticism has focused on the criteria used to determine medical impairment. Health and Human Services Secretary Margaret Heckler has suspended the disability reviews until Congress takes final action.

At a press conference proceeding the meeting, Heckler noted that the SSA had worked with the American Psychiatric Association and the American Psychological Association to develop new criteria for mental impairments. New mental impairment criteria will be ready for release and comment "soon," she added.

The cardiovascular area was selected as the second to be reviewed because about one fourth of Social Security's 2.6 million disability beneficiaries have cardiovascular ailments. About $5 billion of the $17.5 billion paid out in disability benefits last year went to beneficiaries with cardiovascular impairment.

Heckler said that changes in the criteria are not motivated by a desire to save money but from a need to make sure they are fair and equitable.

In a statement issued at the conference, AMA Executive Vice President James Sammons, M.D., noted that AMA had established a Committee on Medical Rating of Impairment in 1956 and between 1958 and 1970 had published 13 separate guides to the evaluation of impairment in various body systems. Collected into a single volume in 1971, the papers have been extensively updated for a second edition published this year.

* * * *

New Seatbelt/Airbag Rule Revealed

The Reagan Administration, under pressure from courts and consumer groups, is requiring automakers to put mandatory restraints or airbags in cars by 1989 if the states don't crack down.

The decision, announced in July by Department of Transportation Secretary Elizabeth Dole, represents a reversal from its position 2½ years ago when the Administration rescinded Carter-era regulations that would have required restraints in some cars in 1982.

Automakers would not have to install airbags or automatically closing seatbelts if states containing two-thirds of the population enact seatbelt legislation within 5 years requiring fines for motorists who don't buckle up, said Dole. However, only New York has approved such a fine.

In recent years, the auto industry has attempted to block such legislation, arguing that the costs exceeded the benefits. General Motors still maintains that Dole cannot tell manufacturers how to meet a performance standard; whereas she can require that a dummy withstand a 30-mph crash, she cannot require airbags, GM says.

Consumer, health, and insurance groups insist that the additional protection is worth the cost. The AMA supports both mandatory seatbelt laws and immediate implementation of rules requiring passive restraints—proferably airbags—in all new cars.

"The AMA has been outspoken in its belief that requirements like these will help improve automobile passenger safety," said Executive Vice President James H. Sammons, M.D. He expressed concern, however, about the provision in the new rule allowing the passive restraint requirement to be lifted if two-thirds of the U.S. population is covered by mandatory seatbelt rules.

* * * *

Firm Pleads Guilty in Pacemaker Scheme

Telectronics, the nation's fifth largest pacemaker manufacturer, pleaded guilty in July to federal charges of paying kickbacks to cardiologists in Rhode Island and Florida.

An estimated 312 Telectronics pacemaker implants were performed by the two doctors who received kickbacks, the company reported.

Telectronics is the second firm to plead guilty in the three-year HHS and FBI nationwide investigations of the pacemaker industry. Pacesetters Inc. of Sylmar, CA, pleaded guilty of similar offenses.

According to U.S. District Court records, Telectronics paid Felix Balasco, M.D., of Providence, RI, between 1979 and 1982 every time he used one of the firm's pacemakers. The company also paid for a $4,800 vacation trip to the Dutch West Indies for Dr. Balasco and a Telectronics sales representative. Dr. Balasco will not comment on the company's statements.

Telectronics also said that in 1980 it paid Clifford Colin, M.D., of New Port Richey, FL, $100 for each of their pacemakers he implanted. The payments were hidden in a $9,065 equipment leasing agreement with Dr. Colin, according to court records. The company said that it leased a vectocardiograph for Dr. Colin; in return, they said, he was expected to implant about 80 Telectronics pacemakers.

Dr. Colin calls their explanation "garbage." The company leased the equipment to his office, he said, so that the physicians could offer free pacemaker testing to the community. The vectocardiography was used five times in two years by local physicians, without charge. Dr. Colin says he made no promise to implant Telectronics pacemakers; the fact that he only infrequently used this brand of pacemaker angered Telectronics salesmen, he said.

In return for the guilty plea prosecutors agreed not to press charges of Medicare fraud against six of the firm's executives. The firm is expected to pay back $243,115 to the federal government.

The physicians have not been charged with Medicare fraud. However, they still are under investigation.

Robert Miller, Colorado U.S. attorney, said additional charges "may be coming down soon" in the pacemaker investigation.

The investigation was prompted in 1979 when a Colorado Springs, cardiologist complained to HHS that he was offered a bribe to use a company's product exclusively.

* * * *

Long-Acting Antibiotic Approved

The first of the new long-acting antibiotics recently approved by the Food and Drug Administration promises to save hospitals time, materials and labor. This second generation cephalosporin cefonicid (Monocid, Smith Kline & French Laboratories) was approved last month for use in urinary and lower respiratory tract infections, skin, bone and joint infections, septicemia and surgical prophylaxis.

It appears to be effective against such gram-negative organisms as *E. coli, H. influenzae, Klebsiella,* and *Proteus,* along with gram-positive organisms such as *S. pneumoniae, S. aureus,* and *S. epidermidis.*

Its most important feature, however, appears to be its long half-life. Patients normally receive between three and four doses a day. By adding a sulfonic acid side chain to the cephalosporin molecule, which slows its release into the blood, researchers developed this new one-a-day form.

Researchers report that use of a long-term antibiotic could cut back on the number of doses of drug per day as well as the number of days of antibiotic use. By reducing the number of doses each day, hospitals could save roughly $5.40 per patient each day; the overall reduction in antibiotic use could save an average of $155 per bed per year.

Additionally, patients could be treated outside the hospital rather than remaining as inpatients.

* * * *

Organ Registry Bill Passes House

The House of Representatives in July overwhelmingly approved legislation that would set up a system of coordinating for donors and recipients or organs.

The House bill, passed 396 to 6, now goes with its Senate counterpart to a conference committee where differences can be resolved. The Senate bill is a more conservative and less costly piece of legislation, because it would simply set up a task force to study the organ distribution problem.

The House bill would establish a computerized registry to match heart, liver, lung, kidney, pancreas, and bone marrow donors to recipients. It would also authorize $40 million in grants over the next four years to strengthen and expand the nation's 110 organ-procurement centers.

One controversial aspect of the bill would provide $30 million over the next two years to pay for immunosuppressive drugs for indigent patients. Opponents say that it is unfair to have the government pay for drugs needed by transplant patients, but not for drugs needed by persons with other life-threatening diseases. Supporters say the drugs are essential to the procedures' success.

* * * *

New Tampon Labels Proposed

Because tampon manufacturers haven't responded to the Food and Drug Administration's two-year drive for voluntary toxic shock ratings on their labels, the agency announced in July that it will propose a regulation rating by number the absorbencies of various products by number. The number will appear on the package with an explanation of its significance.

Findings have indicated that toxic shock tends to occur more frequently in women using foam high-absorbency tampons than in women using the cotton low-absorbency tampons. However, women have little guidance as to which product to choose.

Tampons hold between 5 and 18 grams of fluid, with Tampax Junior at the low end and Playtex Super Plus at the high end. The descriptions of "regular," "super" and "super plus" varied from brand to brand, so that one company's "regular" could be another company's "super."

A task force of tampon manufacturers, consumer groups and FDA representatives had reached an "impasse," according to acting FDA Commissioner Mark Novitch, M.D.

Consumer groups had pushed for standardization of the current descriptive terms rather than numbers.

The FDA preferred the numerical approach because it did not want to regulate the way companies describe their product.

In June, 1982, the FDA required manufacturers to include a warning about toxic shock syndrome on the boxes of their products. The new regulation simply provides quantitative information. The agency plans to launch a consumer education program to encourage teachers in junior and senior high schools to urge their students to use the least absorbent tampons necessary.

* * * *

Incentives for Prevention

A Senate bill introduced in July offers health insurers new incentives to include preventive health care services for children in their plans.

The Pediatric Health Care Incentive Tax Act, sponsored by Sen. John Chafee (R-RI) and endorsed by the American Academy of Pediatrics, would deny tax deductibility to employer group health plans which fail to offer these preventive services.

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If passed, the Act would cover immunizations, blood and urinalysis tests to detect illnesses, and health exams at regular intervals.

"We are not proposing that all sniffles and bruises be covered by this plan," said Paul F. Wehrle, President of AAP. "But because preventive services are not covered by insurance plans, children are not receiving the medical treatment they need."

"Over 90% of all employment groups now have some form of private health insurance. Unfortunately, the focus is on acute care needs. We need to redesign the system to encourage preventive care—and the place to start is with children," said Sen. Chafee.

The extra care would cost employers about $2.50 per month per employee in group health plans. The Act's supporters say that this could reduce long-term costs by eliminating unnecessary hospitalizations: the cost for all services from birth through age 20 would be equal to the cost of one day in the hospital, they contend.

Tax-deductibility of employer-group health insurance plans is the second most costly of taxpayer-subsidized health programs; the government loses $35 billion a year in revenue to ensure that these programs survive. The government should reassess their investments, said Sen. Chafee and Dr. Wehrle, focusing on preventive as well as episodic acute care.

* * * *

Computer Comparisons Between Communities

Early next year health planners, business coalitions and others will be able to purchase a sophisticated software package that compares hospital capacity, per capita health care spending and incidence of various medical procedures among communities.

With the touch of a computer key, for example, a health planner in Maine could see that a child in one community is nearly seven times as likely to have his tonsils removed as a child in another Maine town. Or a rate setter could see that hospital spending per resident in Boston is twice that of nearby New Haven, even though no difference in the quality of care may be obvious.

The software's designers interpret their findings to mean that many current cost control measures—including Medicare's diagnosis related groups and the about-to-be-replaced professional standards review organizations—have mistakenly focused on hospital lengths of stay and unit costs rather than on admissions. They further assert that practice variations and higher per capita health costs are associated with excess hospital capacity and that given proper data, physicians can be induced to reduce excess capacity.

The new software program is based on earlier work by a Dartmouth epidemiologist Jack Wennberg, M.D., M.P.H., on small area analysis of medical practice. Wennberg's studies reflect his background in epidemiology and his belief that comparing defined age and sex adjusted geographic populations is a more valid statistical technique than other approaches which look at single institutions.

More recently, Dr. Wennberg completed studies with similar results in Iowa and in conjunction with Harvard researcher Philip Caper, M.D., has related his technique to DRGs. His works are gaining increasing attention in Congress and in the business and planning communities.

Business groups, which are spreading Wennberg's findings as part of a general push for the collection and disclosure of health care data see it as a useful tool for "purchaser cost management activities." Thus, the Washington Business Group on Health and the National Association of Manufacturers recently sponsored a meeting focusing on data collection, including Wennberg's small area analysis technique, and will sponsor, along with the American Health Planning Association, special seminars demonstrating the technique this fall.

The business groups are urging that proposed confidentiality regulations for peer review organizations be loosened to permit general disclosure of physician specific data. Hospital and medical organizations—including the American Medical Association—have argued, on the other hand, that the proposed rules, which do permit release of hospital specific information, are already too loose. As a result of the controversy, the Reagan Administration is expected to hold off publishing final confidentiality rules until after elections.

* * * *

Physician Attestation Watered Down in New DRGS

Months of protracted negotiations have produced a compromise of sorts on a new physician requirement that accompanied Medicare's move last year to a diagnosis related groups (DRGS) prospective pricing system.

Under the compromise spelled out in newly-proposed regulations to guide the DRG system in its second year, physicians will still have to vouch for the accuracy of the diagnosis listed in the medical records of discharged hospital patients. But, a widely-denounced accompanying statement warning the physician of the consequences of a falsified record will no longer appear in each hospital record. Instead, the physician will be asked to sign an annual statement indicating that he is aware of the penalties for fraud.

Other changes are intended to clarify that physicians are not responsible for the codes the hospital attaches to their diagnoses nor for the accuracy of procedures listed in the hospital record but performed by nurses and other hospital personnel rather than by the physician.

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Choking: The Heimlich Maneuver (Abdominal Thrust) vs. Back Blows

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The National Conference on Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC) held in September 1979 by the American Heart Association, produced a document entitled "Standards and Guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC)" which was published in the *Journal of the American Medical Association (JAMA)*.[1] In one section the maneuvers to be used in management of the acutely obstructed airway were outlined and included three to be used in the following order:

1. backblows,
2. manual thrusts and
3. finger sweeps of the pharynx.

It was also reported that "the conference heard data presented that offered evidence for the following:

1. either backblows or thrusts when used alone may relieve obstruction,
2. neither backblows nor thrusts are always successful,
3. a combination of backblows and thrusts is more effective than either technique used alone.

These data supported the recommendations of the National Conference on Emergency Airway Management sponsored by the National Academy of Sciences—National Research Council in 1976, from which the guidelines of the American National Red Cross and American Heart Association were derived."[1, 2]

In their CPR instruction since that time, the American National Red Cross and the American Heart Association have included the sequence of backblows followed by manual thrusts (either abdominal or chest) and finger sweeps of the pharynx as the recommended order in which to approach the patient who may have an obstructed airway. Doctor Heimlich, who first proposed the abdominal thrust, has joined with others who take exception to this order of events, maintaining that precious time is wasted by backblows and that they are more likely to fix the obstruction than to relieve it.[3] Doctor Heimlich has held this view so strongly that he has withdrawn his name from the maneuver as it has been recommended by the American National Red Cross and those following their recommendations. The Red Cross and the American Heart Association now refer to the Heimlich Maneuver as "the abdominal thrust."[4,5]

In the continuing debate between Henry Heimlich, M.D., and the various committees of the American Heart Association and the American National Red Cross, there is no debate about whether the Heimlich Maneuver has saved lives. The question is whether there is anything to be gained from the use of backblows, either preliminary to or after the Heimlich Maneuver, as has been recommended by the Committee on Emergency Medical Services (ALS/NRC) report on emergency airway management.[2] It has been agreed generally that the abdominal thrust or the Heimlich Maneuver is a procedure that can be applied by lay people easily and quickly without any special equipment and that it has some hope of successfully relieving the obstruction. It will be the purpose of this report to review the scientific evidence which supports the Heimlich Maneuver (abdominal thrusts) and the use of back blows, as opposed to tracheostomy and more sophisticated, definitive instrumental approaches, in the initial management of laryngeal obstruction by a bolus of food or a foreign body.

The back blow has been the time-honored remedy for assisting someone who is coughing after food or liquid has gone down the "wrong throat", or entered the larynx, so that many victims of choking have had this treatment whether they had an abdominal thrust or not. From 1983 to 1969 this was recommended by the American National Red Cross as appropriate first aid treatment for

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This report is not intended to serve as a standard of medical care: standards of medical care which are determined locally and are constantly subject to change are established on the basis of all the several facts of the individual case.

Action of the House of Delegates (1983 Annual Meeting): Report D of the Council on Scientific Affairs *adopted*.

choking. From 1973 to 1978, the Red Cross taught that a back blow was inappropriate first treatment for a choking victim, but since 1979 it has accepted the recommendation of the above mentioned two conferences. Since 1854, there have been many medical opinions warning against back blows.[3]

Experiments in animals and in human volunteers have shown that meat placed below the epiglottis of anesthetized animals could not be dislodged by any of the maneuvers tested. Meat placed at the epiglottis or in the vallecula was most often dislodged by back blows. Abdominal or chest thrusts were not as effective in dislodging the meat, although the combination of back blows followed by abdominal or chest thrusts was more effective than either one alone. When meat was placed in the hypopharynx, finger extraction was successful in 75% of trials in animals and human volunteers.

The recent reference given by the proponents of the back blow for the management of airway obstruction by a foreign body is the report by J.S. Redding, M.D., which makes a careful critique of the Heimlich Maneuver.[4]

He reported on the results of an American Heart Association (AHA), questionnaire which had been mailed to many individuals and organizations in 1978 and 1979 to review their experiences with various methods of resuscitation used on victims of food choking. In interpreting the results of this AHA questionnaire, it was noted that many of the data had to be discarded because of illegibility, ambiguity, or incomplete information. However, some 225 cases could be analyzed in which 16% of the victims were described as unconscious or partly unconscious. In all, there were 386 trials of various maneuvers with 256 classified as successful. Back blows were labeled successful about half of the time when used in a sequence and were successful initially in about 20% of the cases in which it was the single technique employed. There were no adverse consequences. The abdominal thrust, or Heimlich Maneuver, was successful about three-fourths of the time when used in a sequence, and was initially successful in about 44% of those cases in which it was the only technique employed. Adverse consequences included abdominal tenderness, emesis, esophageal laceration, and retinal detachment. Thus, there were successes and failures attributed to both of these maneuvers. There was, perhaps, a higher percentage of initial failures from the back blows than from abdominal thrusts and a greater overall rate of success with the latter but it was recognized that the data left much to be desired. The reports had been submitted voluntarily and were unverified, probably heavily weighted in favor of successful results and generally not reported by clinically trained observers. The true condition of the victim at the time of treatment could be determined in only five cases.[4]

Redding made a strenuous plea for healthy skepticism regarding claims of saving life, and asserted that the reports provided by the AHA questionnaire campaign were undoubtedly as valid as the anecdotal data which have been so often quoted by Heimlich.[3,5] While back blows did sometimes work alone or in combination with other maneuvers, and sometimes even when the abdominal thrusts had failed (so that they could hardly be termed "death blows" as claimed by Dr. Heimlich) Redding concluded that "there is insufficient evidence on which to strongly recommend any of these maneuvers and certainly none sufficient to condemn any other measures."

Thus, it is the general view of cardiopulmonary resuscitation (CPR) experts that the abdominal thrusts may be helpful in treating a choking patient but that the back blow may also work in some instances, taking little time and being free of complications. It could easily be tried first in the hope that *either* the back blow *or* the Heimlich Maneuver would be effective. The Committee on Accident and Poison Prevention of the American Academy of Pediatrics has recommended back blows that may be followed by chest thrusts, and has recommended that abdominal thrusts not be used in any case.[6] The primary concern here was the potential for damage that may be sustained by the large infant liver.

In a preliminary report of a study conducted by the American Red Cross, it was disclosed that questionnaires were mailed to 648 CPR classes in California. The study elicited 1800 case reports, dating from 1976. The results of this study, yet to be published, confirmed the earlier AHA questionnaire results that back blows, which were most effective in children, were as effective in relieving obstruction about as much of the time as were abdominal or chest thrusts.

Thus, while the rationale for the abdominal thrust is good, the experience with its use in the field provides poor documentation of its superiority over the back blow. Both procedures can be ineffective just as each procedure may occasionally work without the use of the other. This position contradicts the long-standing position of prominent bronchoesophagoscopists and otolaryngologists who have maintained that back blows were not effective in removing a foreign body from the larynx, do not have an adequate rationale and in fact, may be harmful.[7,8] It must here be noted that the endoscopist has a different and much broader foreign body experience than that with a large food bolus. His patients have survived the acute episode and his plea is usually for early endoscopy or tracheostomy.

In their discussion of the management of foreign bodies, Tucker and Hollinger[7] stated that "Recently proposed non-endoscopic techniques for foreign body removal are to be avoided (Ritter, 1974): the abdominal thrust (Heimlich Maneuver, Heimlich, 1975) is the single exception." They further noted that "Hospitalization for inversion and back blows to small children to dislodge and expel bronchial foreign bodies leads to unnecessary delay and, as reported, can cause cardiorespiratory arrest: the foreign body that has been dislodged from the bronchus may become lodged in the narrowest portion of the larynx causing complete obstruction."

In a recent report by R.L. Day, M.D., et al[9] a body plethysmograph was used to measure air pressure in the lungs and an accelerometer quantitated the inertial forces produced by back blows. It was found that back blows would accelerate a supraglottal object in a backward and downward direction into the glottic aperture, thus providing a rationale for the notion that a back blow might be harmful for the patient with a foreign body in or above the larynx. In support of other experimental work, there was found to be less increase in thoracic pressure as a consequence of the back blow than with the abdominal thrust. The authors related this action to Newton's Third Law of Motion.

In another preliminary report, Archer Gordon, M.D., has also pursued experiments measuring changes in pressure and flow in the trachea induced by a back blow, an abdominal thrust or a chest thrust in experimental animals. These experiments showed that the back blow induced a large pressure spike in the trachea, but not the sustained pressure and increased flow of air seen with either the abdominal or chest thrusts. He advocated the back blow to loosen the obstructing bolus and the abdominal or chest thrust to expel it and challenged the notion that a back blow would necessarily drive the bolus deeper into the larynx.

None of the experimental work on animals or volunteers is definitive enough to be conclusive. The valuable questionnaire reporting on the experiences in the field with relief of an acutely obstructed airway suggested that abdominal thrusts were possibly more effective than back blows but indicated that either maneuver might be effective by itself. Apparently, the decision to recommend back blows before abdominal thrusts was made because they were easily and quickly done and were not likely to cause complications. [10] It could be added that they hardly need to be taught and are almost part of our culture.

A physician who might be on hand at the time of laryngeal obstruction due to food in the hypopharynx might well consider the value of a simple tracheostomy if the obstruction is complete and is not relieved by the Heimlich Maneuver or a sequence of maneuvers. Many otolaryngologists have suggested this maneuver as being more valuable and more certain to be effective than either the back blow or the Heimlich Maneuver, if the airway is totally obstructed. The finger sweep should not be done blindly, for this could force the food bolus deeper into the hypopharynx toward the glottis. [7, 8]

Conclusion

From its review of the scientific publications in this area, the Council on Scientific Affairs concludes that the abdominal thrust (Heimlich Maneuver) has an excellent rationale and a good anecdotal history of success in the removal of foreign bodies from the acutely obstructed hypopharynx. No one contends that this maneuver does not work, and it has the advantage that it can be and has been taught to a great many lay people.

Back blows in a child and even in the adult have, on occasion, appeared to be effective at stimulating a cough and dislodging the obstructing laryngeal foreign body. This procedure does not lead to relief of the obstruction in the field with any greater frequency than the abdominal thrust. However, it may be more readily applied to many situations with no adverse effects and with little delay. It is obvious that in these emergency situations it is very difficult to determine whether back blows, which could be administered more quickly and conveniently than abdominal thrusts, were in fact helpful or whether the patient might have expelled the obstructing bolus of food without assistance. The evidence that back blows are actually dangerous for the choking victim is certainly not conclusive, but this position is still held by that body of physicians most intimately involved in dealing with laryngotracheal obstruction: the otolaryngologists.

After careful review of this situation, it is apparent to the Council that different practices with regard to the handling of the choking patient have been adopted by different specialty groups. The otolaryngologists reject the back blow, the pediatricians embrace it; the cardioresuscitation experts, including cardiologists and anesthesiologists, feel that the back blow, while perhaps less effective than the abdominal thrust, is safer and worth a try. The latter have now assumed the position that the order of using the back blow and the abdominal thrust is not important as long as both are employed when the first chosen method fails. Doctor Heimlich and his supporters join the otolaryngologists in objecting to the use of back blows at all.

The Council on Scientific Affairs agrees with most authors on the subject that there is no evidence based on experiment or upon case reports that is adequate to settle the controversy that has arisen. The ultimate support or abandonment of back blows must await the development or more persuasive scientific data than has yet been published.

Recommendations

The Council on Scientific Affairs recommends that the American Medical Association adopt the following position with regard to treatment of the choking victim. In first aid management of the obstructed airway it appears that a combination of back blows and abdominal thrusts is more effective than either one alone. The abdominal thrusts may precede the back blows and, if both of these fail, there should be a finger sweep of the mouth and then a repetition of the maneuvers. If all of these maneuvers fail, a tracheostomy should be done immediately.

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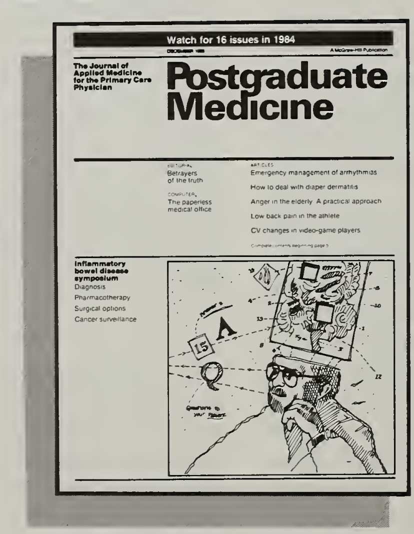

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The President's Page

The Contract

Since beginning my practice of medicine I have always felt that a contract was made between a physician and a patient when the physician and patient accepted their relationship as doctor/patient. This relationship has been well established for millenia and the ethical and legal foundation for it remains sacred to physicians. I feel certain that most, if not all physicians, treat their patients to the best of their ability regardless of the payment potential of the patient.

For this reason, a recent communication from one of the major insurers in this country was found to be shocking to me. Its sole purpose appears to be the intrusion of a fiscal agent into this special doctor/patient relationship. This insurer has introduced what they euphemistically call a hospital Preadmission Certification/Continuing Stay Review which they state "combines our benefits expertise to create a utilization review procedure with significant cost saving potential." It is also stated that this program is national in scope.

The significant portion of the letter deals with the submission of a long form to a company for certification prior to admission of a patient. It also will require employees of companies which enroll in this program to participate, in order to receive maximum benefits—the implied threat being that if a patient refuses to comply, they will not receive maximum benefits. At no time is the quality of care mentioned and there is no proof that this approach will lower costs. In fact, the "Second Opinion" programs, which were introduced years ago in Connecticut to save money on hospitalization, have failed abysmally. Now the insurers have taken a new tack which to me, is blatant interference by a fiscal agent into the doctor/patient relationship which should not be tolerated by either party. In fact, such interference might even be illegal although I am certain that the law department of this major insurance carrier has looked into the legality of this program and has concluded that no laws have been or will be broken.

If this arrangement is legal then it remains up to us as physicians, as well as our patients, to attempt to alter this policy. What right has an insurance company to determine whether a patient should be hospitalized, the type of service to be rendered or the setting in which this service is performed? These are medical decisions and these corporate behemoths have no rights in this regard. Their concern should be only with reimbursement for quality care.

It behooves everyone of us to start talking to our patients, explaining that their insurance company, whose premiums are being paid for by the hard labor of employees and only *through the employers,* and strongly suggest that this approach will not be tolerated. We must all approach employee groups such as unions and inform them of this callous interference into benefits earned with their minds and bodies.

I suspect that every physician in the state has received this correspondence and I would suggest that it be read and a personal plea be formulated to be used on the part of every one of us, to our patients, indicating this gross and callous interference into our relationship of trust with our patients. As I see it, if the program fails, the cost of running it will be added to health care costs and used as an indication that these costs are increasing. If it succeeds, my crystal ball suggests that soon we may all require "cookbooks" dispensed by payors outlining norms of treatment from which deviation will not be tolerated. The quality of care will be compromised, services will of necessity be rationed and in time, the disincentives may lead to mediocrity in our noble profession.

Please talk with your patients and try to maintain this time honored and sacred doctor/patient relationship.

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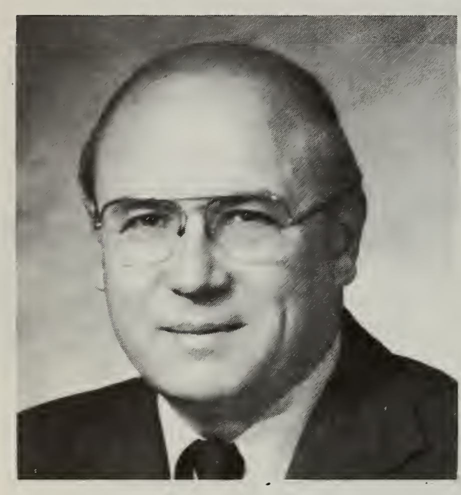

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Reflections From the Dean's Office

What About Mortality?

ROBERT U. MASSEY, M.D.

Since his death this past summer, James Fixx has been the subject of many conversations, especially when there are physicians around to speak with authority on matters of exercise, health, and longevity. What is said in these nervous and often self-conscious exchanges is not especially helpful; jogging is good for you, bad for you, or of indifferent value. The doctors take care to point out that there is little evidence to support any claim, and then talk of moderation and common sense. What is of greater interest is the lurking matter of mortality: "If he hadn't been running every day, we'd have read of his funeral years ago," declared a lawyer. A teacher said jogging made her feel better, "and maybe I'll live longer." Run to ward off death at a time when most of us can count on living longer than ever.

Among the proposals for cutting medical care costs, there are few with the temerity to mention the case for mortality, few that run against the stream to suggest that health may not be the greatest good, may not be worth all this attention and may in fact, like happiness, be achieved only by indirection or by good fortune.

The notion has been around for a long time that contented and good natured persons are healthier and live longer; a corollary tenet ties happiness to hard work and commitment to others, but we hear less about these things now and more about the uses of leisure.

Albert Schweitzer and Arturo Toscanini lived to 90; so did Isaak Walton, and Michelangelo almost made it, but Mozart, Schubert, Shelley, and Keats were gone by 35. At the beginning of the 19th century, life expectancy at birth in Europe was about 30, and, by the end of the century, 45, but since most deaths occurred in the first years of life, these figures tell us little about longevity among adults.

I wondered about the usual age at death for physicians in the 19th century. Fielding Garrison's *History of Medicine* includes about 250 names in the "modern period," approximately from 1800 to 1920; their average age at death was 70, the English and Americans a few months less, the Germans and French a few months more. There were 56 who were 80 or older at the time of death; only one, as you might expect in this group, was under 40. Not bad for a century without intensive care units, and in which tuberculosis and other infectious disease accounted for one-third of the deaths; by reducing mortality in the first decade, medicine and public health have added a score of years to life expectancy at birth; since 1970, another three years, this time mostly by forestalling death.

For comparison, I calculated the average age at death of 250 physicians from the obituary pages of *JAMA* this summer, and found it to be 72 years, or two years more than in the 19th century sample. There were 80 who were 80 years old or older, but more young deaths, maybe auto accidents, possibly coronaries. There were seven women in the second sample, none in the first. I then checked the obituary pages from the spring of 1934, 50 years ago, and found the mean age at death to be 65.

Drawing serious inferences from these figures is unwarranted. In 1934 the *Journal* recorded the causes of death in detail; medical progress in the past 50 years has changed our bills of mortality. But what about the 19th century group? These men made history; did the creative work, the satisfactions of discovery increase their years beyond that of ordinary men, or were they the survivors?

In all of the directions for living coming down to us from the past, not much is said about length of life. Most of the attention is given to striving for wisdom and virtue. When immortality is considered, it seems to be about fulfillment rather than length of life, with growth in wisdom rather than an endless succession of days. Seeking more of the same seems to be terribly expensive, possibly futile, and clearly a burden for our children.

Leon Kass, M.D., has written:

> "Mere continuance will not buy happiness. Worse, its pursuit threatens human happiness by distracting us from the goal(s) toward which our souls naturally point. By diverting our aim, by misdirecting so much individual and social energy toward the goal of bodily immortality, we may seriously undermine our chances for living as well as we can and for satisfying to some extent, however incompletely, our deepest longings for what is best."[1]

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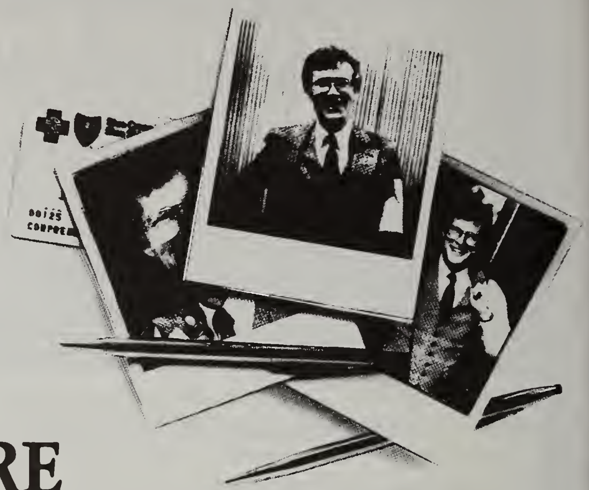

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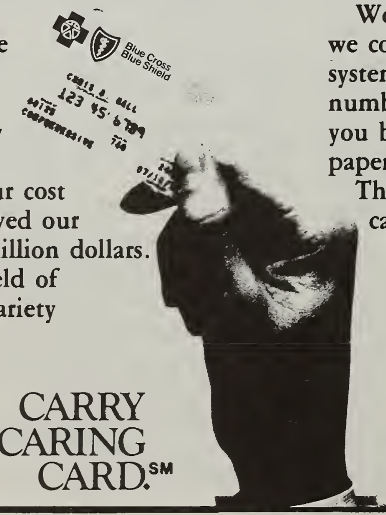

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Editorials

The Medical Association and the School

With all of the celebrating and proclaiming that have marked the Bicentennial of the New Haven County Medical Association, a much less auspicious anniversary has been forgotten. In May, 1884, there were dissolved, by mutual consent, the articles of union between Yale College and the Connecticut State Medical Society which had been the instrument by which the Yale School of Medicine was founded in 1810. The affiliation, presided over by a sort of joint conference committee representing both institutions, and re-enacted several times over the years, had been harmonious, fruitful, and mutually beneficial. It is reported to have died a quite natural death, other methods of over-sight and licensing having evolved, as each of the two participating organizations went its own way in an increasingly complex medical world. One celebratory speaker at the centenary anniversary festivities of the School described the separation as one would the fond parting of two old friends.

And yet, there is reason to believe that the departing embraces may have had more wrestling-grip than hug in them that spring day a hundred years ago. Although Jonathan Knight, who had a foot in each camp, had stated in 1853 that "the result of this arrangement has been eminently happy," there were others who had always been less sanguine about it. As evidence of one side of the issue was the comment of the School's first Professor of Surgery, Nathan Smith, that "Yale would do better without the assistance of the Medical Society"; on the other was the concerted campaign of that department's more recent chairman, Francis Bacon, to destroy not only the relationship, but the school itself. Bacon's resignation as surgical chief in 1877 marked the beginning of a period of rancor and animosity between our profession's town and gown that reverberates still, in the medical affairs of New Haven County.

In time, the anger and bare-toothed snarling were replaced by a state of ambivalence. This, in turn, gave way to the most crippling situation of all—a prolonged period of mutual ignoring by each party of the other. Fortunately, throughout all of this time, there were outstanding leaders from both groups who continued to act on their convictions, indeed their certainties, that mutuality and friendship were in the best interests not only of the two institutions but of the people of Connecticut as well. Their names deserve to be remembered and honored: for the Medical School, there were Herbert Thoms, William Carmalt, Ira Hiscock, and that most visionary of deans, George Blumer. For the State Society there were Walter Steiner, Louis Nahum, Stanley Weld, and Creighton Barker. Of course, there were others, but they never did number a large band.

Recently, we have begun to sense that there are new winds just starting to stir in the air of New Haven County and of the entire state. Not yet strong enough to disperse more than a bit of the torpor that was left to us by the heavy heritage of the last hundred years, the airstreams are nevertheless fresh and gusty; they have already blown away just enough of the old cloudiness so that we are beginning to see the future a trifle more clearly. Although still a bit wary, perhaps wondering what all the fuss was about, faculty members of the School are taking a more active role in the Society, as both institutions are coming to a renewed recognition of how much we have in common, and how few are the real differences of substance between us; even our respective styles seem less disparate than they did just a few years ago. Perhaps one day not too far off, we can return to a friendship not unlike the one which was described by Dr. Knight, who was Yale's Professor of Surgery at the same time he was the first president of the organization that was soon to become the American Medical Association. In an introductory lecture to the medical students, he spoke of the relationship between the School and the State Society: "Each has regarded the other as a laborer in the endeavor to promote and advance the interest of medical science."[1] For Connecticut physicians and their patients, that day would bring the New Jerusalem.

Sherwin B. Nuland, M.D.
Guest Editor

REFERENCES

1. Knight J: A Lecture Introductory to the Course of Lectures in the Medical Institution of Yale College, New Haven, p 13, 1853.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Magnetic Resonance Imaging: New Promises, New Problems, Many Questions

The advent of magnetic resonance imaging (MRI) described by Hawkins and Cinti in this issue of *Connecticut Medicine* promises a new round in the battle against disease and, in all probability, a new confrontation between technology and the political-social realities of finite resources. While there is little doubt that MRI will be an important diagnostic modality in many situations, there is absolutely no doubt that this technology is complex, unproven, and expensive. It seems likely that we are again entering an era of potential conflict much sooner than expected after the computed tomography battles of the 1970s.

Many questions remain to be answered:

- What type of technology is appropriate for clinical and research use? Can both functions be combined in the same facility or is this a compromise which will degrade each purpose? This is of more than trivial interest since currently the difference in cost between a low-priced (!) clinical unit and a large unit capable of biochemical analysis is estimated to be $1,000,000.[3]
- Is technology at present sufficiently established and advanced to make purchase of this expensive instrument economically feasible and worth the risk of obsolescence? Comparison with the problems of the early CT scanners is much too recent to be forgotten.
- How should these machines be purchased? A budget of $2,500,000 for purchase, renovation, and other start-up expenses for a clinical unit is considered appropriate.[1] Hospital-consortium financing is an attractive model, but staffing of such a facility may be a problem. Siting of such a shared purchase will be sure to evoke strong interest—perhaps the development of mobile units will be one solution.
- Should this technology be free-standing in an imaging center or attached to a hospital; purchased and controlled by physicians or by profit-oriented entrepreneurs; operated for the benefit of patients or to provide research information for continued development?

The above are only a few of the questions that can be raised. They are all legitimate and important and the needs of society and the individual patient must be balanced. The Health Systems Agency of North Central Connecticut, the Connecticut Hospital Association,[2] and the Commission on Health Care and Hospitals have all made statements or are studying the question.

There is no doubt that a struggle between practitioners, investors, the health care establishment, and society is in the offing. We can hope that the lessons learned during the 1970s will help provide a speedier and less confrontational solution through understanding and cooperation, so that it will be the patient who benefits.

M.B. Ozonoff, M.D.

Department of Radiology
Newington Children's Hospital
Newington, CT

REFERENCES

1. Bradley WG, Opel W, and Kassabian JP: Magnetic resonance installation: Siting and economic considerations. Radiology 151:719-721, 1984.
2. Connecticut Hospital Association: Guidelines for the introduction of nuclear magnetic resonance technology into Connecticut. April 9, 1984.
3. Freedman GS, Stephens WH, and Fisher B: Economic considerations in MRI. Appl Radiol 55-64, May/June, 1984.

Medicolegal Briefs: Bylaws Contract

In a written opinion, a Florida Trial Court has held that medical staff bylaws, once approved by the governing board of a hospital, become a contract between the medical staff and the hospital and can only be amended as provided for in the medical staff bylaws and not unilaterally by the governing board of the hospital. The court issued a Writ of Mandamus requiring the hospital to provide an immediate medical staff election in accordance with the medical staff bylaws of the hospital.

The governing board of the hospital, a for-profit corporation, approved bylaws adopted by the medical staff on October 26, 1978. The medical staff conducted its elections under these bylaws annually at the December meeting of the medical staff. However, in December 1983 the hospital administrator appointed the medical staff officers for 1984 pursuant to an amendment to the Board of Trustees bylaws. Thereafter, this lawsuit was filed, seeking to force the hospital to permit the medical staff to elect its own officers.

The court found that the medical staff bylaws conformed with Florida law and regulations and also with the requirements of the Joint Commission on Accreditation of Hospitals. Then, citing numerous cases, the court stated:

> "The modern view holds that the Medical Staff Bylaws, when approved by the Governing Board of the Hospital, become a contract between the hospital, operated by the Board of Trustees, and the physicians composing the Medical Staff."

In issuing the Writ of Mandamus, the court found that neither "the Board of Trustees nor its administrator had the authority nor the right to appoint the Medical Staff Officers and those officers appointed by the Board of Trustees, while acting as such Medical Staff Officers under such appointment may be *de facto* Medical Staff Officers, but are not the *de jure* Medical Staff Officers" of the hospital. *Khalil A.I. Cassimally, M.D. v. Lawnwood Medical Center,* a Florida Corporation. Case No. 84-134-CA-18 in the Circuit Court of the Nineteenth Judicial Circuit, in and for St. Lucie County, State of Florida Opinion dated May 21, 1984.

—*AMA Hospital Medical Staff Section Newsletter,* August 1984.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

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CALL
SEMI-ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1984 Annual Meeting of the House of Delegates will be held at the Sheraton-Bridgeport Hotel, Bridgeport commencing at 12:30 P.M. on Thursday, November 15.

Joseph S. Sadowski, M.D.
Lawrence B. Ahrens, M.D., Speaker of the House
Norman A. Zlotsky, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides:

Resolutions may be introduced by any Active or Life Member or student members or postgraduate physician members of the Society, in compliance with the following provisions:

a. All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.

b. Component county associations or the student members or postgraduate physician members, whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.

c. Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.

d. Any business which does not qualify as regular business in accordance with the foregoing provisons may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.

COUNCIL MEETING

Wednesday, July 18, 1984

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbott, Ahamed, Ahrens, Alisberg, Beck, Bobruff, Czarsty, Dardick, Doctor, Freedman, Friedberg, James, Kamens, Kaess, McDonnell, Mendillo, Orphanos, Petrie, Ragusa, Reyelt, Jr., Sadowski, Scheer, Sweet, Villa, Waldron and Zlotsky.

Also present: Dr. Fabro, Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Meister (NHCMA), Mr. Coffey (HCMA), Mr. Schuman (NLCMA) and Mrs. Eslami (President, Auxiliary).

Absent were: Drs. Bonner, Canzonetti, Concannon, Seide, Sullivan, Jr., and Whalen, Jr.

Professional Liability Programs

The sole purpose of this meeting, which was held at 6:30 in the evening, was to determine the Society's course of action pertaining to several professional liability options available. The Council had received, prior to the meeting, materials distributed by Marsh & McLennan, representing a claims made proposal with St. Paul as the carrier; a renewal offer made by the CNA with a rate increase of approximately 41%; and an alternative proposal offered by the CSMS insurance consultant, Mr. John Dorsett of American Health Systems, to launch a CSMS captive insurance company.

Also distributed was a report from the CSMS Committee on Professional Liability and some late submissions from CNA and AAW Physician Plans.

Mehdi Eslami, M.D., Chairman of the CSMS Committee on Professional Liability, reviewed the three alternatives for members of the Council and answered questions. Following a lengthy question and answer period, Dr. Eslami proposed the following three motions for consideration:

1. CSMS act immediately to activate Connecticut Medical Insurance Company (CMIC).
2. CSMS enter into contract negotiations with American Health Systems (AHS) to implement and operate CMIC.
3. CSMS immediately appoint an Ad Hoc committee to interact with AHS personnel.

It was VOTED to approve all three motions with only one dissenting vote on the first motion. It was also VOTED that the Chairman of the Council would appoint the Ad Hoc committee.

It was noted that AHS would make a final recommendation on whether to proceed with the activitation of the CMIC no later than August 17, 1984. If the recommendation is not to proceed, AHS will cease all work unless otherwise directed by CSMS. The cost estimates to be incurred on the preliminaries to be undertaken by AHS is estimated to be no greater than $80,000.00.

NOTE: Guy W. Van Syckle, M.D, Chairman of the Council, appointed the following Ad Hoc committee: Drs. Joseph S. Sadowski, Chairman; Lawrence B. Ahrens, Sultan Ahamed, W. Raymond James, Kevin Dowling, Jerome K. Freedman and James P. Orphanos.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on July 18, 1984. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

NOTICE TO CONTRIBUTORS

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **INFORMATION FOR AUTHORS.** This material may be obtained from the *Journal* office, Tel.: (203) 865-0587. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:

J. Alfred Fabro, M.D., Editor
Connecticut Medicine
160 St. Ronan Street
New Haven, Connecticut 06511

IN MEMORIAM

APTER, HARRY, George Washington University, 1934. Dr. Apter was an internist in the Hartford County area since 1936. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died July 22, 1984 at the age of 77.

FARRELL, JEAN E., Georgetown University, 1952. Dr. Farrell was a pediatrician in the Fairfield County area since 1953. She was a member of the senior staff at both Stamford and St. Joseph hospitals. Dr. Farrell was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died July 3, 1984 at the age of 56.

MERRIMAN, HENRY, Columbia College of Physicians and Surgeons, 1936. Dr. Merriman was an otolaryngologist in the New Haven County area since 1936. He was on the attending staff of Waterbury Hospital from 1946 to the present and was chief of the medical staff there between 1959 and 1961, serving as staff president in 1970. Dr. Merriman served his country during World War II and was discharged with the rank of major. He was a founder of the Pan American Association of Oto-Rhino-Laryngology and Broncho-Esophagology. Dr. Merriman was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died July 17, 1984 at the age of 74.

READ, FRANCIS A., Yale University School of Medicine, 1924. Dr. Read was a surgeon in the Fairfield County area since 1937. For 25 years, he was attending surgeon and then chief surgeon at Greenwich Hospital. He remained an honorary staff member of the hospital, working in its emergency room until 1979. Dr. Read was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 27, 1984 at the age of 76.

ROOT, SOPHIE T., Cornell Medical School, 1919. Dr. Root was an endocrinologist in the Hartford County area from 1936 to 1976. She was a member of the Hartford Hospital Visiting Staff and a consultant of the Institute of Living and the Newington Children's Hospital. She was the first woman on the Hartford Hospital physician's staff. Dr. Root was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died July 6, 1984 at the age of 90.

WELHAVEN, ARNE, Oslo University, 1947. Dr. Welhaven was a psychiatrist in the Hartford County area since 1953. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died June 29, 1984 at the age of 65.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

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FAMILY PRACTICE/GERIATRICS

Wanted: Physician to become associated with and in time assume Family Medicine/Geriatric practice in lower Fairfield County. Woman preferred but not exclusively. Write, CSMS, FP/MB.

INSTITUTIONAL MEDICINE

VA-Yale Substance Abuse Fellowship—The West Haven VA Medical Center is again offering a two year Fellowship in substance abuse beginning in July 1985. The major goal is to train the physician to understand and treat substance abuse in a comprehensive manner. The Fellow will learn to diagnose and treat the illness and how to develop comprehensive programs for the effective treatment of these disorders; and ample opportunity for collaborative research. Training will take place in the VA Alcoholism Program and the Drug Dependence Unit of the Connecticut Mental Health Center, major teaching facilities of the Psychiatry Department at Yale University School of Medicine. Available to physicians who will have completed residency training (board eligible or certified) in psychiatry, family practice, internal medicine or neurology by July 1, 1985. Those interested should contact James Nocks, M.D., Fellowship Director and Chief, Alcoholism Program, Associate Clinical Professor of Psychiatry, West Haven, VAMC. (203) 932-57711 ext. 522. An Equal Opportunity Employer.

INTERNAL MEDICINE

Growing, federally qualified HMO in Southwestern Connecticut seeks BC/BE Internist. Emphasis on personalized, cost-effective, preventive medicine. Competitive salary, comprehensive fringe benefits, teaching appointments to university-affiliated hospitals. Submit C.V. to: Ron Blumenfeld, M.D., Medical Director, Connecticut Health Plan, 4000 Park Ave., Bridgeport, CT 06604. No phone calls please.

Farmington Valley, CT. Internist needed immediately to join 4 internists in active office and hospital practice. Guaranteed minimum salary with full partnership opportunity. Write CSMS, IM/JR.

Board eligible/certified internist needed to join a group of 14 internists in a federally qualified pre-paid staff model HMO. A sub-specialty in pulmonary or infectious disease or in allergy is preferred. In our 12th year of service with 37,000 members we are affiliated with Yale-New Haven Medical Center. Excellent pay and a unique benefit package. Submit CV and salary requirements to: Vice-President for Medical Affairs, CHCP, 150 Sargent Dr., New Haven, CT 06511. An equal opportunity employer. M/F.

INTERNAL MEDICINE/FAMILY PRACTICE

Physician needed to join as a partner who is either board eligible or certified in internal medicine or family medicine to join an intermediate care center in Waterbury, CT. Please reply to Eastside Medical Center, P.O. Box 365, Cheshire, CT 06410.

MISCELLANEOUS

Physicians wanted for New Urgent Care Center in Branford, CT. The Coastline Medical Center, opening August 1, 1984, is equipped with Lab, X-Ray, Defib., etc. Pleasant surroundings. Malpractice insurance provided. Salary competitive. Full or part time. Send resume or phone: H. Ardolino, M.D., River Rd., Essex, CT 06426. (203) 481-0818.

Retiring physician seeks successor to take over medical office on rental or percentage basis. Location is two blocks from Windham Hospital. Contact, Mr. Sheridan Vernon, 185 Birch St., Willimantic, CT 06226 or phone (203) 423-4451.

PHYSICIANS—ER, IM, FP. Either BC/BE for expanding physicians owned operated episodic care clinics in Connecticut. Join other excellent physicians, take part in ID and other ambulatory care studies. Competitive salary. Directorships and stock options available. Remarkable Opportunity. Write, CSMS, MISC/DRC.

OBSTETRICS/GYNECOLOGY

B.C. or Eligible OB/GYN wanted to join busy practice in beautiful Northwest Connecticut. Salary guarantee followed by partnership. Respond OB/GYN-RCS.

PEDIATRICS

Pediatrician wanted, West Hartford, CT. Seeking board-eligible or certified pediatrician to join solo practitioner with established practice, now starting up second office. Excellent medical and cultural environment. Affiliated with Hartford area hospitals including University of Connecticut Health Center. Contact Susan Markel, M.D., 720 Hopmeadow St., Simsbury, CT 06070. Telephone (203) 651-9345.

Pediatrician. Board eligible or certified. Needed immediately for full time position to join an established HMO in Farmington. Doctors form their own independent corporation. Hartford Hospital is primary referral hospital. Contact Eugene Fantl, M.D., Chief, Pediatrics, KFHPC, 99 Ash St., East Hartford, CT 06108 or phone (203) 568-8500 ext. 223.

PRACTICE FOR SALE

Internal medicine. Well established practice available October 1, 1984. Fully equipped office in medical building in Hartford. St. Francis hospital area. Write Physician, P.O. Box 7-516, West Hartford, CT 06107 or call after 6:00 P.M. (203) 521-3991.

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PHYSICIANS WISHING TO PRACTICE IN CONNECTICUT

ALLERGY

July '84. Age 33. Nat'l bds. AB elig. MD, University of Rochester, Rochester, NY; Int., Res. and Fellowship, Children's Hospital of Buffalo, Buffalo, NY. Available for any type practice. Write, Christopher Randolph, M.D., 307 Summer St., Buffalo, NY 14233.

ANESTHESIOLOGY

July '84. Licensed in Connecticut. Age 34. FLEX. AB elig. M.B.B.S., Delhi University, New Delhi, India; Int., Lady Hardinge Hospital, Delhi and State University of New York at Buffalo, Buffalo, NY; Res., State University of New York at Buffalo. Write, Hansa H. Bhayani, M.D., 95 Scamridge Curve, Buffalo, NY 14221.

July '85. Age 33. Nat'l bds. AB elig. MD, Albany Medical College, Albany, NY; Int., University of Kentucky Medical Center (Surgery); Res., Cambridge Hospital, Cambridge, MA. Prefers group or associate type practice. Write, Howard Feder, M.D., 58 Selkirk Rd., Apt. 16, Brookline, MA 02146.

FAMILY PRACTICE

May '84. Presently in practice. Age 56. MD, University of Bologna, Italy; Int., St. Boniface General Hospital, Winnipeg, Manitoba, Canada; Res., Health Sciences Center, Winnipeg. Prefers group, associate or institutional type practice. Write, Vito P. Girgenti, M.D., 9 Monk Rd., Warwick, RI 02889.

July '85. Age 30. Nat'l bds. MD, University Autonoma of Guadalajara, Malisco, Mexico; Int., New York Medical College and St. Joseph Hospital, Stamford, CT; Res., Somerset Medical Center, Somerville, NJ. Prefers group or associate type practice in a small to medium-sized community. Write, Gerard J. Fitzpatrick, M.D., 1140 L Easton Ave., Somerset, NJ 08873.

Immediate available. Age 47. FLEX. MD, Catholic Medical College, Korea; Int., University Hospital, NJ (OB/GYN); Res., Psychiatry, Pathology, General Practice, NJ (information available on request). Prefers solo, group, institutional or industrial type practice in a small or large-sized community. Write, Jong H. Kim, M.D., 127 Garfield Ave., Jersey City, NJ 07305.

INTERNAL MEDICINE

GASTROENTEROLOGY. Sept. '84. Age 32. Nat'l bds. AB cert., (ABIM). MD, Albany Medical College, Albany, NY; Int. and Res., St. Louis University Hospitals, Louis, MO, (IM); Fellowship, Washington University Medical Center, St. Louis, MO (Gastro.). Prefers associate, group or solo type practice. Has worked with Physicians Multispecialty Group. Write, Harry D. Burack, M.D., 5548 Waterman Place, St. Louis, MO 63112.

July '84. Age 56. Licensed in Connecticut. Nat'l bds. AB cert. (PSY); elig. (IM); MD, NYU—Bellevue Medical School; Int. and Res. (IM), Greenwich Hospital, Greenwich, CT and Metropolitan Hospital, NYC; Res., (Psychiatry), Metropolitan Hospital, NYC. Prefers group type practice in a small community. Write, Peter B. Schneidau, M.D., 17A Appletree Lane, Darien, CT 06820.

Aug. '84. Age 28. AB cert. MD, Universidad LaSalle, (Mexico City); Int. and Res., Sinai Hospital, Baltimore, MD. Desires group, associate or institutional type practice. Write Eduardo Anhalt, M.D., 6A Spring Rock Rd., Branford, CT 06405.

PULMONARY. July '85. Age 30. Nat'l bds. AB cert. (IM); AB elig. (PUL). MD, Downstate Medical School, State University of NY; Int. and Res., Shore University Hospital and Memorial Hospital Sloan-Kettering Cancer Center, NY; Fellowship, Memorial Sloan-Kettering Cancer Center (IM) and Montefiore Hospital and Medical Center/Albert Einstein College of Medicine (PUL). Seeking to join Pulmonary, Pulmonary/Internal Medicine or Multispecialty Practice or Group in a medium to larged-sized community. Write, David M. Breidbart, M.D., 50 Hillpark Ave., Apt. 1R, Great Neck, NY 11021.

July '85. Age 28. Nat'l bds. AB elig. D.O., NJ School of Osteopathic Medicine, NJ; Int. and Res., John F. Kennedy Memorial Hospital, Stratford, NJ; Fellowship, New Jersey Medical School Affiliated Hospital. Has a chief interest in critical care units. Desires solo or associate type practice in a small to medium-sized community. Write, Robert L. Werner, D.O., 148 Reservoir Rd., Parsippany, NJ 07054.

ORTHOPEDICS/SPORTS MEDICINE

July '84. Age 35. Nat'l bds. AB elig. MD, Georgetown University School of Medicine; Int. and Res., St. Lukes/Columbia University College of Physicians and Surgeons, New York City, (General Surgery); Mt. Sinai Hospital, New York City (Orthopedics); Fellowship, Cincinatti Sports Medicine. Prefers solo, group, associate or institutional type practice. Write, George McGinniss, M.D., 105 5th Ave. #8E, New York, NY 10003.

PEDIATRICS

July '85. Age 27. Nat'l bds. AB elig. MD, University of Connecticut, Farmington, CT; Int. and Res., J.W. Riley Hospital for Children, Indiana University, Indianapolis, IN. Prefers solo, group associate or institutional type practice but is obligated to locate in, or service a, National Health Service designated Health Manpower shortage area. Write, A.E. Hertzler Knox, M.D., 7773 Swallowtail Dr., Indianapolis, IN 46224.

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June '85. Licensed in Connecticut. Age 62. Nat'l bds. AB cert. MD, Int. and Res., McGill University, Montreal, Canada; Fellowship, McGill University (Pathology). Has a particular interest in *Review* or *Administrative* capacity. Write, CSMS, SUR/JBC.

July '84. Age 36. Nat'l bds. AB elig. MD, Medical University of South Carolina; Int., St. Vincent's Hospital, NY; Res., St. Vincent's Hospital and Bronx-Lebanon Hospital Center, NY. Prefers solo, group or associate type practice. Write, Barry G. Jordan, M.D., 260 Garth Rd., Scarsdale, NY 10583.

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New Britain Cardiac Rehabilitation: Thirteen Years' Experience

CHARLES N. LEACH, JR., M.D. AND LINDA M. SHANNON, M.A.

ABSTRACT—In October, 1982, we celebrated the tenth anniversary of the New Britain General Hospital/New Britain-Berlin YMCA Cardiac Rehabilitation program. This paper discusses the changes which have occurred in the theory and practice of cardiac rehabilitation and their impact on the New Britain program during its 13 year existence. The areas affected include: theoretical rationale, potential candidates, exercise modalities, exercise prescription, organizational structure, patient progression, safety and monitoring. This paper is also an introduction to the two papers which follow that were presented at the tenth anniversary conference celebration.

Introduction

In May, 1977, we reported in these pages the structure, scope and goals of our community's Cardiac Rehabilitation Program. In the report which follows, we discuss the changes which have occurred in the theory and practice of cardiac rehabilitation and their impact on our New Britain program.

The New Britain General Hospital Cardiac Rehabilitation Program was begun in 1971. Our therapeutic goals were and remain the restoration of cardiac patients to optimal physical, psychological, occupational and social well-being as permitted by functional capacity. Initially the program consisted of outpatient stretching and flexibility exercises supervised by a physical therapist, and interval bicycle ergometer exercise supervised by a cardiovascular nurse. An inpatient program was soon added that offered progressive exercises through twelve stages supervised by a physical therapist. In October, 1972, the program expanded to include a walking-jogging component at the New Britain YMCA. This collaborative effort was the second such in New England and the first in Connecticut. The present program has grown dramatically to include 150 active participants with the original four-phase structure.[1] In total, we have worked with approximately 712 participants in the past 13 years. (Table 1)

Table 1

THE NEW BRITAIN CARDIAC REHABILITATION PROGRAM PHASE STRUCTURE

PHASE	*ACTIVITY*	*LOCATION*
I (Figure 1)	Flexibility Exercises Ambulation Stair Climbing	Hospital Inpatient
II (Figure 2)	Warmup & Flexibility Exercises Walking	Home and Physical Therapy Department
III (Figure 3)	Bicycle Ergometer	Physical Therapy Department or YMCA
IV (Figure 4)	Jogging	YMCA

Rationale

On undertaking our program in 1971, we anticipated that exercise and behavior modification therapy of cardiacs would achieve important psychological and physical benefits. We expected that collateral coronary circulation would develop under the influence of intermittent ischemic stress. We anticipated that improved survival of patients in cardiac rehabilitation programs would be demonstrated by large-scale prospective studies. We expected to increase our patients' anginal thresholds, and we anticipated such important psychologic benefits as relief of depression and modification of a Type A personality. We expected to favorably alter health-related behavior with reduction of certain cardiac risks such as smoking and poorly-controlled hypertension.

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Phase I

Phase III

Phase II

Phase IV

by

Since that time, the idea that physical training stimulates growth of collaterals remains unproven,[2] and exercise has not been shown to cause regression of coronary atherosclerosis. Efforts to document efficacy of rehabilitation programming in prolonging life have yielded suggestive but not statistically significant results.[3,4,5] Efficacy of cardiac rehabilitation in terms of patient behavior modification and risk factor abatement,[6,7] has been documented as has modification of the Type A behavior pattern.[8] Return to pre-infarction employment and leisure activities has been enhanced.[9,10] Numerous studies have documented improvement in anginal threshold,[11] and it is our impression that we have achieved similar success in our program. We have not worked with patients suffering from severe angina, and this problem remains to be addressed.[10]

Potential Candidates

The original intent of the Cardiac Rehabilitation Program was to serve patients with recent myocardial infarction. Few patients had undergone coronary bypass surgery at that time, and we did not encourage the enrollment of non-infarct patients with angina. Those with serious arrhythmias, unstable angina, congestive failure or uncontrolled blood pressure were not accepted and this policy remains unchanged. We have continued to accept candidates of all ages.

Initially, patients with poor left ventricular function were not enrolled. Early in our 13 years' experience, we recognized that patients with left ventricular aneurysm responded well to physical conditioning. Since then, we have realized that those with poor left ventricular ejection fractions could also respond and benefit symptomatically.[12]

Other potential candidates we now seek out whom we earlier prohibited entry are those with three vessel disease and marginal left ventricular function. We now encourage patients with claudication to enter the program in order to gain the benefits of improved skeletal muscle oxygen uptake.[13] Symptomatic improvement has been shown to result from habitual aerobic activity. We also seek out the anxious hypochondriac, the Type A personality, and the undermotivated obese hypokinetic patient. We actively encourage the participation of those with pulmonary disease, diabetes and Class 2 angina pectoris, conditions which benefit from aerobic training.[14,15]

Recently, we have begun to physically condition patients earlier after their myocardial infarctions, moving them quickly through Phases I and II into Phase III. Because of the demonstrated hazards of training patients with blood pressure anomaly during exercise testing,[16] we often refer this group for angiography to assess the need for revascularization surgery before enrolling them in the physical conditioning program.

Finally, it is necessary as participants remain for years in the program to determine criteria for termination of exercise therapy or to reassess expectations regarding flexibility, strength, and aerobic conditioning. We have attempted to moderate the initial enthusiasm of our participants into acceptance of the limitations of physical conditioning that evolve with aging. We must take into account the effects of osteoarthritis, diminished aerobic capacity, lung disease, neuromuscular problems, and increased fat weight.[17]

Exercise Modalities

In 1971, exercise for cardiacs consisted of brief high intensity leg and trunk work performed in an abrupt, ballistic fashion. Initially, the primary form of aerobic exercise was the walking-jogging Phase IV program at the YMCA. The necessity of incorporating a warmup, cooldown, and flexibility exercises into the regimen was undocumented at that time. It was felt that intermittent exercise of high intensity would limit fatigue and maintain enthusiasm as well as accomplishing physical conditioning more quickly. We have since realized that exercise of longer duration and moderate intensity is more safe and pleasurable. Enhanced weight control is an additional benefit of prolonged moderate intensity aerobic exercise.

Because of theoretical hazards, arm work and all isometrics were avoided initially.[18] However, bluecollar work requires arm strength. Therefore, we have directed our attention to conditioning both the upper and lower extremities following myocardial infarction. Upper body exercises include the use of light weights for strength, range of motion for flexibility, and the arm crank ergometer for endurance. Schwinn Air-Dyne bicycles (Figure 1) incor-

porate an arm component, and they have been enthusiastically accepted by our clientele. These modalities are particularly important for the increasing numbers of post-coronary bypass patients who return to our hospital for conditioning.

We have come to acknowledge that some of our exercises such as situps, abdominal curls, and wall calf stretches incorporate slight isometric exertion. As with arm training, we now recognize that mild isometric exertion can be accomplished safely and does not lead to an undue risk, increase symptoms, or arrhythmias. [19] Its inclusion lends diversity and relieves boredom for our participants.

Particularly for our aging clientele, we have recognized the importance of static stretching, warmup and cooldown exercises. [20] By avoiding bouncing, deep knee bends and straight-leg-situps, we attempt to prevent lower extremity joint and back trauma.

Exercise Prescription

Stress testing was originally done solely with the bicycle ergometer. For the past several years we have moved entirely to treadmill testing done with the Naughton protocol within the first two weeks after myocardial infarction and subsequently with the standard Bruce protocol. Early low level stress testing allows early progression into Phase III of the Rehabilitation Program with attendant close supervision and continuity of patient contact. Intervals between followup stress tests have been extended from six months to one year without misadventure.

Our original exercise prescription consisted of strict adherence to a target heart rate during brief bursts of aerobic activity, either jogging or cycling. Maximum target heart rates during Phases I and II were established at 110-120 beats/minute. Because of recent evidence that beta adrenergic blockers enhance survival after myocardial infarction, the majority of our patients now take these medications,[21,22] Beta blockers reduce heart rate and blood pressure during exercise at submaximal and maximal levels. Consequently, cardiac rehabilitation participants are now stress tested on their medications in order to determine a safe target rate. The prescribed target heart rate becomes a general recommendation for a range of heart rates to be adjusted by the exercise physiologist and cardiovascular nurse supervisor during activity sessions. Target heart rates have thus become approximate rather than precise recommendations.

A valuable recent addition to exercise prescription has been the Borg Scale of Perceived Exertion. [23] (Table 2) The patient subjectively estimates his level of exertion during maximal exercise testing and the rating is then incorporated into the exercise prescription. The Borg Scale promises to be particularly useful for the beta-blocked group in whom heart rate is a less reliable indicator of exercise intensity and for the group who will be exercising on their own. Unfortunately, the Borg Scale is of limited use for those Type A participants who tend to push too hard and underestimate their level of exertion. For them, we rely more on the target heart rate and on the supervisor's estimate of the client's exertional level.

Table 2
BORG SCALE

6	
7	Very, Very light
8	
9	Very Light
10	
11	Fairly Light
12	
13	Somewhat Hard
14	
15	Hard
16	
17	Very Hard
18	
19	Very, Very Hard
20	

Borg G, Noble B: Perceived Exertion. Ex & Sport Sci Rev (2):131-153, 1974

Regardless of the details of exercise prescription, we are assiduously careful not to allow cardiacs to exceed 85% of their symptom limited maximal heart rate. We adhere to this policy to ensure safety, prevent orthopedic injury, and to control participants' exercise habits and attitudes.

Organizational Structure

We continue to utilize the multidisciplinary team approach to cardiac rehabilitation. The program is now implemented by a variety of allied health professionals who have specialized training in their own fields as well as in the rehabilitation of cardiac patients. The following disciplines are represented: cardiovascular nursing, physical therapy, dietary, social work, pharmacy, and physical fitness specialists. All members of the team recognize the importance of group activities including both educational and exercise sessions for psychosocial support. We continue to encourage significant others to attend education and exercise classes.

We rely heavily on the insights of our social worker for optimal psychosocial rehabilitation.

Patient education and exercise supervision remain the province of cardiovascular trained nurses. Physical therapy has taken a more aggressive approach to management of the Phase I inpatient program. Social service, dietary, and the pharmacy continue to make important contributions to educational components of Phases I and II.

The program administrators are the cardiologist medical director (CL) and the exercise physiologist coordinator (LS). Recent inclusion of the exercise physiologist has improved communication among team members, physicians, families, hospital care-givers and employers and added insight to exercise prescription and progression. Coordination of the program has enhanced accountability, record keeping and patient evaluation and progression.

Throughput and Graduation

The hospital stay for cardiac patients has become briefer. Therefore, progression through the original Phase

I twelve-step protocol has been telescoped to nine steps of progressive mobilization. The intensity of education on coronary heart disease and its prevention as well as behavior modification measures are correspondingly increased to allow the abbreviated hospital stay to have a sufficient impact on the patient-client.

The initial outpatient phase (II) has been shortened. As YMCA personnel have grown in numbers and experience, we have been able to insist that patients not remain overlong in the hospital-based Phase III without specific clinical indications.

Though their expenses are not indefinitely covered by insurance, we have allowed patients to remain in the YMCA program as long as they wish, and, when necessary, in hospital Phase IIIA which is specifically intended for high-risk patients. Our program costs have remained low enough to allow indefinite stay with minimal economic burden on our clientele.

The safety of aerobic exercise without supervision for selected coronary patients remains controversial, and we do not encourage individual aerobic exercise.[24] We specifically discourage unsupervised exercise for patients with suspected or documented three vessel or left main disease, arrhythmia, low cardiac output, or exercise blood pressure abnormality. We also do not encourage strong Type A personalities to exercise independently. For patients with documented single vessel disease and fairly normal treadmill response we feel that unsupervised aerobic exercise is relatively safe if patients adhere to exercise guidelines. In these cases we perform periodic stress testing and consent to individual exercise after careful discussion of relative risks and benefits.

Safety, Monitoring, and Workup

Until recently we did not conduct formal intake interviews of new participants. Computerized intake data now include blood analysis, risk factor profile, demographic data, and medical history. Since the earliest days, we have not employed telemetry monitoring of exercising patients. We have relied instead on pulse checks, frequent blood pressures during exercise sessions, and on ECG monitoring via defibrillator paddles when indicated.

Our cardiac arrest frequency is 1 per 25,000 hours of exercise. [25] There have been three cardiac arrests at the New Britain YMCA since the inception of the program. All have been resuscitated without difficulty, gone on to cardiac revascularization, and later have continued exercising. Cardiac arrest was not predicted by arrhythmias during stress tests or exercise sessions. Our experience profiles these participants as younger, Type A males who jog, who exercise at more than 85% of their maximum predicted heart rate, are not on propranolol, and have a blood pressure anomaly during stress testing. We are particularly careful with our clients who exhibit these characteristics and we insist on strict adherence to exercise levels less than 85% of symptom limited heart rate. We have in recent years preferred bicycle ergometer exercise to jogging because of the ease of supervision and monitoring.

Conclusion

We have described the evolution of the New Britain Cardiac Rehabilitation program in response to changing patient needs and to increased understanding of exercise physiology. While its original goals remain firmly in place, the means of attaining them have become more flexible, and the multidisciplinary approach to cardiac rehabilitation has become more highly developed and more effective. We have cared for 712 patients for a total of approximately 71,200 hours of exercise at the hospital and YMCA. The program has served as an exemplar of good health practices and therapies for our community and all of New England. From it have developed other community efforts to utilize exercise and good health behaviors in preventive cardiology. We anticipate a continued outreach to new groups of patients for whom exercise therapy may prove useful.

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The Heart Patient After Hospitalization: Social and Psychological Factors in Life After a Heart Attack

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ABSTRACT—After treatment in the hospital for a heart attack, the long-term recovery, rehabilitation, and quality of life of heart patients are mediated by various social and psychological factors as well as by physical disease processes. This paper reviews a selected series of influential elements in the post-hospital lives of heart patients which may help shape long-term outcome. They include the work situation, the family, self-image and sexuality, religious and spiritual influences, the physician-patient relationship, and use of health care and cardiac rehabilitative services.

Each year in the United States about 700,000 persons leave the hospital after having survived a heart attack. Given recent spectacular developments in medical therapies and technology, the proportion of patients surviving is likely to grow substantially over the next decades. However, as a Task Force report of the National Heart, Lung, and Blood Institute pointed out, "Many of them—survivors of recent heart attacks—do not recover to the extent of their full potential because of physiologic, psychologic, and/or sociologic complications of coronary disease which are barriers to rehabilitation."[1]

After discharge from the hospital, the problems commonly facing the heart patient include not only those of continuing physical recovery but often the need for adjustments and adaptations in various areas of life as well. They include work, economic circumstances, family relationships, love and sexual relationships, leisure activities, and personal habits, sometimes involving smoking, diet, weight control, exercise, alcohol consumption, and other aspects of style of life.

Once they have experienced heart attacks, how do heart patients from differing cultural and socio-economic backgrounds deal with the illness? What is the nature of their adjustment as they cope over the years, some experiencing minimal symptoms, others with such enduring severe discomfort, pain, impairment, and possibly disability? Although new studies have been emerging in recent years, reviews of the research literature on long-term adjustment processes and problems of persons with heart disease still provide only limited empirical data on

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these issues.[2,3,4] Most of the best studies center on relatively short-term periods and on limited issues, such as return to work. The continuing paucity of adequate empirical data on the needs, life situations, quality of life, and psychosocial problems of heart patients make the tasks more difficult for physicians and other health professionals engaged in developing policy and programs for long-term rehabilitation and management of heart patients.

This paper reviews briefly some of the principal elements which may influence the post-hospital rehabilitation of heart patients. Its second purpose is to point up some continuing issues and questions which serve to illustrate information gaps which can hamper program planning and development of a sophisticated model of the recovery and rehabilitative process in cardiac disease.

Orientation and Approach

In this presentation, I make use of a conceptual model which permits examination of various principal life areas which may be influenced by the illness and which may affect the progress of the recovery and rehabilitation process in turn.[5,6] Briefly, it considers the patient as the core actor in a model visualized as a series of life areas and involvements.

The focus is on only a selected few of the life areas, centering for illustrative purposes on such aspects as work, family, physician-patient relationship, selected psychological characteristics and use of services. Some illustrative materials are drawn in part from previous empirical work by the author in long-term studies of heart patients in collaboration with Sol Levine, Ph.D.[6,7] as well as from current research on heart patients and the retirement decision.[8]

Work

A classic indicator of progress in the recovery and rehabilitation of heart patients has been the criterion of "return to work." Indeed, in many ways the capacity to perform work roles has pervasive and critical effects on quality of life, including the economic, social, and psychological state of individuals. In the research literature, a generally favorable picture emerges concerning rate of return to work after myocardial infarction. Though percentages vary among differing studies, findings generally suggest that about 85 percent of previously employed men are back in the work force again by one year after the heart attack.[2,3]

Work appears to operate differently as an element in recovery among various classes of heart patients, as differentiated by social, economic, and psychological criteria. For example, the rate of return to work is less among blue-collar workers, younger workers, and patients with marked depression and anxiety.[2,3] Differences between patients of varying occupational backgrounds may be particularly distinctive. For example, in a study of 345 heart patients after a first myocardial infarction, Croog and Levine found that at five months after the heart attack, 80 percent of executives and professionals had returned to employment, but only 42 percent of blue-collar workers had done so.[7]

The meaning of work for heart patients is another aspect which bears on their rehabilitation. While work may be an important aspect of their lives, it can also be regarded as a threat to health. In the study of heart patients just cited,[7] high proportions (85 percent) of the men indicated their belief that elements of their work—either its emotional stress, its physical stress, or a combination of both factors—were important in causing their heart attack. Thus, it appears that in returning to work, large proportions of the patients also considered that they were re-engaging in activities which might further threaten their lives and health. Such readiness to blame the work situation for recurrence of illness can alter the quality of the work experience itself for the returning patients. Beyond this, it may be inimical to employability of heart patients and to employer-employee relationships.

A second issue relating to the meaning of work for heart patients involves their willingness and ability to alleviate stresses at work by reducing their hours of employment. In our study of 345 patients, one fourth of those blaming stress at work reported that prior to the first heart attack they worked 50 to 70 hours or more per week. When we interviewed these men eight years later, some interesting differentiation by occupational level was evident. Among those survivors still in the work force, 50 percent of the executives and professionals reported still working long hours.[6] However, few of the employed clerical and blue collar workers did so at that time (11 percent). Such data imply the need for understanding the differing meaning of work among patients from varied occupational groups and the unwillingness of some patients to change, even while believing that work represents a life risk.

The Family and the Course of Recovery and Rehabilitation

After discharge of the heart patient from the hospital, the family is perhaps the most important group in shaping the course of recovery and rehabilitation. For example, the family provides a setting in which various types of support are given—emotional and social support, services, and material aid. How the patient conforms to the physician's recommendations on diet content, fat restriction, and reduction in salt intake can be strongly influenced by both the preferences of the food preparer and by the willingness of other family members to alter their own food patterns at home to conform with the patient's prescribed diet. Further, family members can also affect the long-term course and recovery by encouraging the patient's preventive health practices, such as exercise, smoking cessation, and stress reduction.

Along with these positive potentials for shaping the recovery and adaptive experiences of the heart patient, the family can also serve as a source of stress and a negative influence. Marital conflict which preceded the illness can be exacerbated by it. Dependency and psychological invalidism can be encouraged in the patient by a spouse or other family members who take on new roles and dominance in the household.

Research reports have been documenting the kinds of problems which heart disease introduces into the home.[9, 10, 11] In our own study of heart patients, we have reported as well some data which bear on the quality of relationships in the home and the potential influence on rehabilitation.[6] When asked to rate a series of factors in their lives which had a role in causing their first heart attack, as many as one-fifth of the married men noted that problems with their wives were important. Among those men with children, about 25 percent indicated that "upsetting problems with children" were important in the etiology. Further among the survivors eight years later, essentially the same findings emerged. Other evidence suggests that a number of other men felt the same way on these matters but chose not to report their feelings.

If wives and children are aware that the heart patient has such views about them, their own response to the patient may be complicated with resentment, guilt, rage defensiveness, and/or overprotectiveness. It seems clear that understanding the role of the family in the recovery of heart patients requires examination of the complex relationships and emotional currents in the home which has not yet been fully reflected as yet in the research literature.

Another dimension relevant to the male patient's recovery and role in the family is his capacity for sexual performance. Feelings of self-worth and manliness, confidence in fulfilling usual family roles, as well as deeper unconscious elements of ego structure are among the factors which may be tied to sexual performance. The problems can be relatively pervasive. For example, as Kolodney, Masters and Johnson note, "There is a substantial occurrence of impotence and diminished libido in male cardiac patients."[12] Ironically, how these characteristics link to long-term recovery processes after a heart attack has been rarely explored.

Physicians may be reluctant or may not have time to discuss matters relating to sexual activity with the post MI patient, both in the cases of male and female patients. For example, in our study of heart patients cited earlier, only a small percentage of patients (less than 5 percent) indicated at the end of the first year after the heart attack that they had had such discussions. Though the perception and recollection of the patients may have been inaccurate, it is notable that a substantial proportion of the physicians themselves—about 50 percent—did not report giving such advice when questioned on the matter.

Psychological Traits and Personality as Resources

Psychological and personality factors affecting response to coronary disease have been the object of new and burgeoning research in recent years. However, the empirical evidence is still unclear in regard to ways in which the nature of ego structure, defense mechanisms, emotional health or illness, morale, the Type A behavior pattern and related factors may be associated with longer term social and psychological adaptations of heart patients or their rehabilitation. Mood disturbance such as anxiety and depression may have negative relationships to longer term social and psychological functioning and rehabilitation.[3, 4] On the more favorable side, positive affect toward the illness and its meaning, high morale, and relative absence of feelings of helplessness and powerlessness have been reported as related to measures of positive functioning and "adjustment" to the heart attack.

In our own study of heart patients, as one example, they were asked for their assessment of the meaning of the illness at one month after discharge.[6] About 50 percent indicated at that time despite problems and concerns associated with the illness, they also saw gains and advantages coming out of the experience. Such factors were noted as gaining new perspective on life, chances to change their life style and reduce cardiogenic risk factors, and feelings of being drawn closer to their wives and families. In interviews one year later and eight years later, such patients were more likely to score higher on measures of social and psychological functioning than those patients who earlier had more negative approaches to the illness.

Feelings of Guilt, Sin and Their Meanings for Long-Term Recovery and Rehabilitation

One area not usually considered in empirical studies of long-term adjustments to heart disease is the meaning ascribed to the illness by the patient, and its relationship to his spiritual and religious life. How the patient feels about the role of supernatural forces in causing a heart attack, for example, can be a powerful factor in affecting his response to the condition itself, the treatment, and his post-hospital course. It can contribute in some cases to feelings of hopelessness, helplessness, and resignation in line with a patient's conviction that he is being punished and nothing can be done. The view that the illness is payment for past sins can profoundly affect willingness to comply with the therapeutic regimen.

The proportions of patients who at least in part perceive etiology of their heart attack in terms of retribution and sin may not be minor. For example, in our earlier study of patients in Boston shortly after their first heart attack, Levine and I found that 20 percent directly or indirectly ascribed their illness to payment for sin and to punishment for doing wrong in life. Eight years later this view of etiology was reduced among survivors, but was still reported by 11 percent. About half of all the patients ascribed it to the "Will of God" after the heart attack, and this number included those who had ascribed the punishment-retribution notion as well.

These data on perceptions of etiology emerged in the somewhat impersonal context of a survey research interview. Under circumstances of an established relationship with a trusted physician or member of the clergy it seems likely that the percentages might be even higher.

In the case of post-hospital cardiac patients, how such perceptions affect recovery, rehabilitation, and the doctor-patient relationship needs to be explored. Thus, it may be important in long-term management of the cardiac patient to consider "spiritual health" and the sense of spiritual guilt and despair as part of the picture, along with the physical, psychological and social aspects of the illness.

The Physician as Resource

The relationship between physician and patient has been identified as one of the primary elements in promoting successful recovery and rehabilitation after a heart attack. The importance of the physician's role both in the acute and chronic phase of heart disease is so well recognized that it needs little review here. Ironically, given its primacy, it is surprising that only a relatively small degree of empirical research centers directly on the doctor-patient relationship, different styles of interaction, and on communication processes in relation to "outcome" or rehabilitation status among populations of heart patients.

Loyalty to the physician and continuity in the doctor-patient relationship has been found to be somewhat more pervasive than commonly assumed. Publicity about dissatisfaction with health care, criticisms of physicians as a group and the increasing incidence of malpractice suits have sometimes tended to overshadow the more favorable aspects of therapeutic relationships. The patient's satisfaction and interest in continuing care from the physician may be an important one in helping maintain a steady show of progress and adjustment following his heart attack.

Our study of heart patients found a high degree of loyalty and satisfaction with physicians. [6] After eight years, about two thirds of the patients still received treatment from the same physician, even though many intervening factors occurred, such as retirement or death of the original physician, or removal of some patients from their original communities.

Once the patient has left the hospital, generally only indirect evidence is available regarding the physician-patient relationship. Data available from a national survey of physicians suggest that the typical office visit of the heart patient is relatively short. The time spent in face-to-face contact amounted on the average to approximately 13 minutes, [13] and nearly one third of the visits occupied 10 minutes or less. Only 5 percent extended for over 30 minutes. It appears from such data that little time may be allotted for discussion between doctor and patient of social, psychological, or situational issues.

Use of Rehabilitative and Other Services in the Community

Formal services and facilities at the local, state and federal levels are an important potential resource in the recovery and rehabilitation of heart patients. Such services include cardiac rehabilitation units, job training and placement agencies, employment counseling and guidance, self-help and counseling groups such as Sharing and Caring, individual and family counseling or therapy services, and informational and health educational programs.

Despite the growth of such services over recent decades, it appears that these facilities have been used by or are available to only a limited sub-segment of the total number of cardiac patients who might benefit. Considering data from various sources, it would appear that over recent years most heart patients have not made use of formal agencies and institutional services during their post-hospital recovery. Data from a survey by the Social Security Administration in 1972 [16] showed that an estimated 3.2 million persons were identified as disabled due to cardiovascular diseases. Within this group, an estimated 60 percent were classified as severely disabled—unable to work regularly or at all. Within the total group of heart disease disabled, however, only 13 percent reported that they had received formal rehabilitation services of some type. Services included job training and placement assistance, employment counseling and guidance, and physical therapy. Degree of severity of disability was not related to use of services. [14]

These national data on limited use of services are reflected in other studies as well. For example, Croog and Levine [6, 7] reported that among 300 patients in the year after a first heart attack, most (72 percent) had no contact with agencies or services other than the hospital. Among the remainder, the majority made use of employment services for job placement for relocation. Similarly, eight years later, the surviving population reported minimal use of cardiac rehabilitation and related services, either during the previous year or during the full eight-year period of the study. This occurred even though many had been rehospitalized for heart disease or continued to suffer physical, social, and economic problems associated with their illnesses. Other studies seem to portray the same pattern of minimal use of formal resources in the United States and in other countries. [9, 14]

The number and capacity of cardiac rehabilitation units is limited. In 1976, the American Heart Association listed only 148 facilities in its Directory of Rehabilitation Units in the United States. [15] These were located in 35 states; for 15 other states, no units were listed. Further, about 60 percent of the units were located in six states, and most were in large metropolitan areas. Taking into account the possibility of incomplete listings and classification, such data imply that at the time heart patients in many sections of the country had limited access to services. Although the number and type of the units have increased in recent years, discrepancies persist between geographic areas in availability of services.

Conclusion

The range of problems which may face heart patients in their social, psychological, and economic accommodation to the illness can be varied and complex, involving ongoing factors in their lives such as those at work, in the family, in interpersonal relations as well as in their health habits, and style of life. Over the past decade or so, new attention has been focused on those issues and problems of post-hospital recovery and rehabilitation of the cardiac patient, as well as on the development of cardiac rehabilitation programs and facilities. Progress in these areas has not been as marked, of course, as in the development of technologies, therapies, and pharmaceuticals for the treatment of the acute stages of coronary disease. Nonetheless, there have been substantial changes, and many have occurred within the recent life span of such programs as that in New Britain.

In the treatment and management of the coronary patient in the chronic phase, the physical, social, and psychological issues are closely intertwined, affecting the life chances as well as the quality of life of the patient. Many of these problems can be aided through the use of institutions, agencies, and personnel resources such as rehabilitation programs, exercise programs, family agencies, employment counselors, job-training centers, dieticians, self-help groups, and others. In the past, as studies have shown, large numbers of cardiac patients did not receive such services because of problems of availability, access, and referral, However, increasingly such programs, facilities and personnel can constitute an important resource for the physician to call upon through referral and for the patient to use over the course of his continuing life after a heart attack.

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Getting Well in the 1980's: The Second Generation of Cardiac Rehabilitation

CARL FOSTER, PH.D.

Abstract—This article reviews the historical and methodological issues pertinent to understanding the state of art in cardiac rehabilitation. It discusses various issues in the future development of cardiac rehabilitation including: goals, selection of patients, exercise testing, exercise prescription, surveillance, prevention, ventricular function. The report concludes with a discussion of potential future directions in the field of cardiac rehabilitation.

Historical Perspective

Cardiac rehabilitation is a mongrel of several progenitors including: medicine, nursing, physiology, physical education, physical and occupational therapy and psychology. The fundamental concept was first suggested with the development of the "armchair" method of treating patients following acute myocardial infarction by Levine and Lown in 1951.[1] Their clinical insight regarding the deleterious effects of bedrest, confirmed much later by laboratory studies[2,3] provided a framework for the aggressive early treatment of patients with cardiovascular disease which is the hallmark of contemporary cardiac rehabilitation. The first systematic plan for the rehabilitation of cardiac patients was presented by Hellerstein and Ford in 1957[4] and appropriately marks the birthdate of this facet of health care. The concept of monitored exercise to provide surveillance in addition to reconditioning was introduced in the early 1960's.[5] Together with the development of the concept of preventive cardiology in the late 1960's,[6,7] the concept of conditioning and surveillance provided the background for the rapid proliferation of rehabilitation programs beginning in the early 1970's. Evidence that cardiac rehabilitation is reaching its maturity may be found in the sponsoring of World Congresses' in 1977 and 1981 and the development of a specialty journal, *The Journal of Cardiac Rehabilitation,* in 1981. Although no discrete professional organization has yet emerged at a national level, the tremendous growth of the American College of Sports Medicine within the past five years can be traced primarily to an influx of members employed primarily in adult fitness and cardiac rehabilitation. Thus, we are at the end of the first generation (25 years) of Cardiac Rehabilitation. Where are we going in the second generation?

There are several basic issues related to both the historical context of cardiac rehabilitation as well as in its likely future. These are: a) goals, b) selection of patients, c) exercise testing, d) exercise prescription, e) surveillance, f) primary and secondary prevention, and g) ventricular function. Each poses particular challenges and needs to be considered in the evolution of our field.

Goals

The fundamental goals of cardiac rehabilitation programs, depicted in Table 1, are not greatly changed from those first enumerated by Hellerstein and Ford[4] a generation ago. We all want our patients returned to their optimal physical, social, emotional, psychologic and vocational status. Although most of our younger patients return to work, and demonstrate remarkable improvement in their physical status, we have been comparatively unsuccessful at treating the social, emotional

Table 1

FUNDAMENTAL GOALS OF CARDIAC REHABILITATION

1. Patient Restored to Optimal Status
    - Physical
    - Social
    - Emotional
    - Psychological
    - Vocational
2. Provide for Orderly Convalescence.
3. Provide for Surveillance and Feedback Regarding Treatment.
4. Secondary Prevention.

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and psychologic squeale consequent to the acute presentation of cardiovascular disease. Certainly future growth must involve helping our patients deal with the reality of their illness, accept the efficacy of their recovery, as well as tolerate residual impairment remaining after medical/surgical treatment has achieved maximum effect.

Selection of Patients

Historically patients presenting to cardiac rehabilitation programs have been recovering from myocardial infarction or suffering with stable angina pectoris. The presentation of large numbers of post myocardial revascularization surgery patients beginning 10 years ago, together with more aggressive early treatment of myocardial infarction patients has served to shift the temporal sequence of rehabilitation toward relatively more acute patients. The development of percutaneous transluminal coronary angioplasty and intracoronary thrombolysis will undoubtedly provide the rehabilitation team with even more relatively acute, stable patients and will allow increased aggressiveness in treatment.

Jones[8] at Duke University has demonstrated that patients with angiographically significant coronary artery disease who respond normally during exercise radionuclide angiography are at very low risk for fatal events. In the absence of limiting symptoms, these patients may represent ideal candidates for the 1980's version of maximal medical management. Likewise, the realization that cardiovascular disease is most successfully treated during its early, relatively symptomless stages (Figure 1) may serve to provide us with significant numbers of patients with abnormal exercise test results or even with only risk factors as criteria for program entry. This may, in turn, force the inevitable union between preventive and rehabilitative exercise programs.

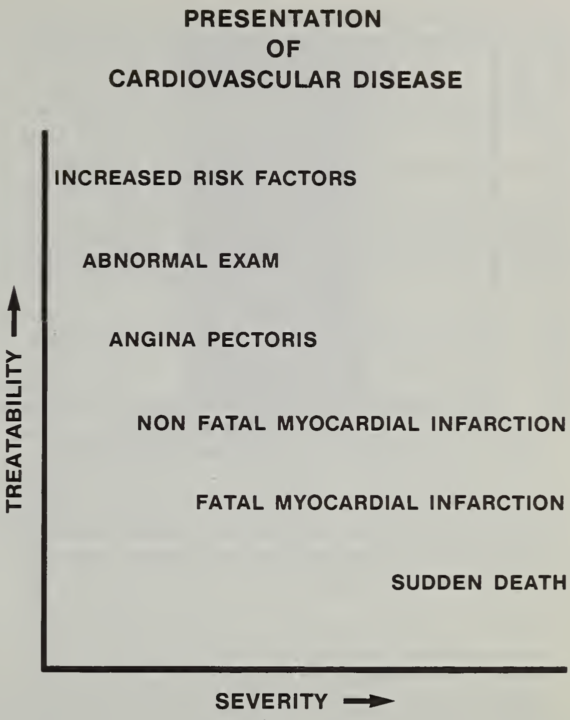

Figure 1
Presentation of cardiovascular disease relative to its potential severity and potential treatability. One value of exercise programs may be to move the patient downward and to the left on this continuum.

Exercise Testing

Certainly we have come a long way since Master first developed the concept of exercise electrocardiography and a standard exercise protocol.[9] However, the basic purpose of exercise testing has not changed greatly. Exercise testing is of proven value in evaluating the effects of medical interventions such as drug therapy,[10, 11] exercise programs,[12, 13] and balloon angioplasty.[14] It is also useful in identifying medically stable patients who remain at risk following myocardial infarction and who might be candidates for early aggressive surgical management.[15, 16] Exercise testing is still of unproven value relative to determining prognosis following revascularization surgery,[18] and one avenue of future development in this area must be the early identification of the surgical failure.

Table 2
GUIDELINES FOR EXERCISE PRESCRIPTION

Prescription	*Phase I*	*Phase IIa*	*Phase IIb**	*Phase III*	*Phase IV & Healthy Adults*
Frequency	2-3 x/daily	1-2 x/daily	5-7 x/weekly	3-5 x/weekly	3-5 x/weekly
Intensity	MI: RHR + 20 CABGS: RHR + 20 SS	MI: RHR + 20, RPE 13 CABGS: RHR + 20, RPE 13 SS	70-75% HRR SS	70-75⅛ HRR SS	70-75% HRR SS
Duration	MI: 5-20 min CABGS: 10-30 min	MI: 20-45 min CABGS: 30-45 min	30-45 min	30-60 min	15-60 min
Mode	ROM, TDM, bike strairs	ROM, TDM, bike	ROM, TDM, bike arm ergometer	walk, bike, swim selected sports	walk, bike, swim selected sports

*Six to eight weeks following the acute clinical episode, a symptom limited exercise test is performed. Exercise intensity is then based on heart rate reserve (HRR) and more aggressive upper extremity exercise is allowed. MI = myocardial infarction patient; CABGS = coronary artery bypass graft surgical patient; HR = heart rate (beats/minute); RHR = (standing) resting heart rate; ROM = range of motion exercise; TDM = treadmill; RPE = rate of perceived exertion (Borg); SS = signs/symptoms. In patients with ECG evidence of myocardial ischemia or exercise.

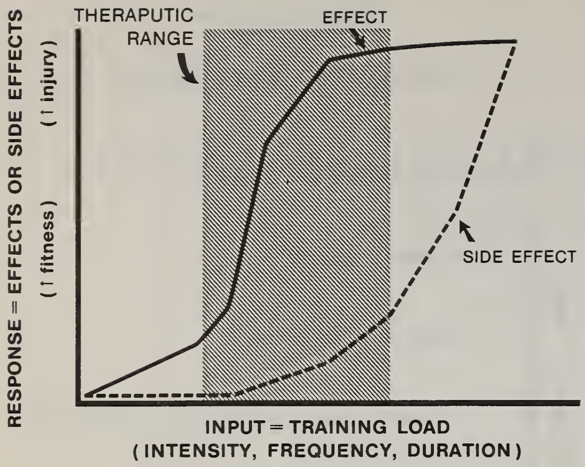

Figure 2
Schematic representation of the major issue in exercise prescription. The goal for the clinician is to achieve maximal effects with minimal side effects. The therapeutic range represents the best compromise of these two results of training load.

Exercise Prescription

The basic principles of exercise prescription for healthy individuals are well established and are founded on a solid background of controlled research.[18] Although fairly well codified, the principles of exercise prescription for cardiac patients are to some degree common sense adaptations, and conservative applications, of these well established rules. For the most part, the principles of exercise prescription for cardiac patients (Table 2) revolve about preferential use of exercise duration rather than intensity as the method for increasing the training load. They also include exercising at a heart rate below that required to elicit signs or symptoms.

It is important to understand that prescription of exercise is made on the same conceptual basis as prescription of medications: achieving maximal effects (increase in work capacity, reduction in risk factors) with minimal side effects (injury, loss of interest, cardiovascular emergencies) (Figure 2). The so-called "therapeutic level" represents the best compromise between effect and side effect.

Surveillance

As indicated earlier, the cardiac rehabilitation program provides a unique opportunity for patient surveillance and for evaluating the effectiveness of changes in medical management. The proven effectiveness of monitored rehabilitation in eliciting medical problems and significant dysrhythmias[19-21] suggests their value even if the reconditioning and educational facets were not operative. The joint availability of monitored Phase II programs and non-monitored gymnasium based Phase III programs suggests that the patient may be moved back and forth as the relative needs for surveillance and reconditioning change.

Prevention

The contribution of regular exercise to the primary prevention of cardiovascular disease is well documented.[22, 23] Less discussed is the apparently greater effect of exercise on reducing the incidence of fatal cardiac events as compared to total cardiovascular disease. When we consider that fatal presentation of disease is the least treatable (Figure 1), the effect of exercise programs on primary prevention becomes particularly meaningful.

The effects of exercise rehabilitation on secondary prevention is less clear. Although common sense dictates that it should be of value, currently available research data are contradictory and severly limited by questions of statistical power.[24-26] One of the challenges for the next generation of rehabilitation is to determine if secondary prevention is realistically possible.

Ventricular Function

Left ventricular function is a factor of clear importance relative to the prognosis of patients with cardiovascular disease. Since therapeutic interventions such as myocardial revascularization surgery[27, 28] and treatment with nitrates and beta blockers[29, 30] improve ventricular function, it was hoped by many that exercise training might also improve ventricular function. Several studies now available indicate, however, that left ventricular function (as defined by ejection fraction) is not particularly enhanced by participation in a conditioning program.[31-34] The mechanism for the improved work capacity with training has not been defined but apparently does not involve changes in ejection fraction.

To counter this disappointment, however, is the observation that patients with severe left ventricular dysfunction may do very well in exercise programs.[35] Clinical evidence of left ventricular failure may be more important in predicting poor responses to training than the absolute value of the left ventricular ejection fraction. However, even the patient with repeated episodes of congestive failure may be a candidate for rehabilitation since the surveillance available in this setting may allow for closer control of medical management in these patients.

Future Directions

There are several issues that urgently need to be addressed relative to the immediate future of cardiac rehabilitation programs. These are, in no particular order, the possibility and implications of nearly universal rehabilitation, criteria for program entry and exit, professional standards for paramedical professional workers and the source of economic support for rehabilitation programs. Primarily because of inherent conservatism with this new form of treatment, and secondarily because of economic realities, many contemporary rehabilitation programs tend to focus only on the highly monitored, staff intensive Phase I and II levels. The less expensive, but still useful Phase III and IV programs are still far from adequately utilized. We need the development and clarification of guidelines for medically supervised and non-supervised exercise programs.

Hopefully, certification programs sponsored by organizations such as the American College of Sports Medicine will allow development of paramedical professionals to the point where physician and nurse supervision of exercise programs is not obligatory. The attitude of the insurance industry to rehabilitation programs is still very inconsistent and tends to support only the more staff intensive types of programs. It is probably of considerable importance to the immediate future development of rehabilitation programs to develop a coherent set of guidelines for third party reimbursement that can be applied regionally if not nationally. Hopefully, organizations such as the American Heart Association and the American College of Sports Medicine can lead in the quest for unified stance from the third party support structure.

Thus cardiac rehabilitation has come a long way during its first generation. It is a clearly defined subdiscipline ready to take its place in the practice of medicine. How effectively this will be accomplished will depend on the resolution of many of the issues discussed here as well as others not identified.

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Important Advances in Clinical Medicine

Epitomes of Progress—Physical Medicine and Rehabilitation

The Scientific Board of the California Medical Association presents the following inventory of items of progress in physical medicine and rehabilitation. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in physical medicine and rehabilitation that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Physical Medicine and Rehabilitation of the California Medical Association and the summaries were prepared under its direction.

Mechanical Prophylaxis of Deep Vein Thrombosis

Short-term and long-term complications in dealing with deep vein thrombosis have been known for many years and range from mild swelling in the lower extremities to sudden death. It is obvious that the best treatment is prophylaxis and multiple means have been used over the years including, but not limited to, range-of-motion exercises, low doses of heparin and mechanical compression.

Mechanical means of prophylaxis of deep vein thrombosis in the form of elastic stockings have been in use for many years with varying degrees of success. Their mechanism of action is by circumferential compression of soft tissues, with the greatest amount of pressure being distal and progressively decreasing as the stockings go higher up the leg.

Unfortunately, the diameters and configuration of patients' lower extremities vary greatly, which leads to some compromise in the fit of the devices. After a number of washings, the elastic garments also tend to stretch and lose their uniform compressive effect.

The advent of custom-made elastic garments overcomes these problems to a large extent, but the high cost and difficulty in application make them impractical for many persons.

In the mid 1970s, the intermittent compression pump was introduced as a means of prophylaxis for deep vein thrombosis. The mechanism of action is by intermittently inflating a balloonlike garment over the lower extremities. By doing this, one can introduce intermittent compression of the calf veins of the leg. The mechanics of the device are said to simulate the muscle pump mechanism, which is lost or reduced in those persons who are paralyzed or confined to bed.

In 1980 Rossi and associates did a prospective controlled study in 18 patients with spinal cord injuries to establish the incidence of deep vein thrombosis using daily examination, impedance, plethysmography, fibrinogen scans and venograms. The incidence of deep vein thrombosis in untreated patients was 78%.

In 1982 the study was repeated using intermittent compression of the lower extremities as a means of prophylaxis, with a decrease in the incidence of deep vein thrombosis from 78% to 33%.

In those patients using external pneumatic compression in whom deep vein thrombosis did develop, all clots were in the popliteal or calf veins as opposed to 23% being in the iliofemoral veins in the untreated group.

There were no noticeable complications from the use of external pneumatic compression. The devices are easy to use, simple to apply and can be left in place 24 hours a day except for skin checks and bathing. The only significant precaution is that they must be applied low enough toward the ankle to prevent venous pooling.

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The routine use of intermittent pneumatic compression of the lower extremities of bedridden patients is a very promising addition to the current methods of preventing deep vein thrombosis and in some institutions has already become a routine method of prophylaxis in postoperative and bedridden patients.

Joel S. Rosen, M.D.

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Rossi EC, Green D, Rosen JS, et al: Sequential changes in factor VIII and platelets preceding deep vein thrombosis in patients with spinal cord injury. Br J Haematol 45:143-151, May 1980.

Delayed Effects of Poliomyelitis

Most physicians have thought of poliomyelitis as a relatively static disease that stabilizes after the inital febrile stage of paralysis. That opinion was shared by their patients, who found that after months or years of diligent exercise they had increased strength so that they were able to discard braces or walk after being confined to wheelchairs. Now, 30 and 40 years after the polio epidemics, increasing numbers of polio survivors are finding themselves unable to perform self-care tasks or to do the work that they had been doing for years. To polio survivors who believed their condition to be stable, these unexpected limitations are confusing and distressing.

In the past 18 months we have seen 35 polio survivors whose common symptoms were fatigue, pain, decreasing strength or loss of function. Ages ranged between 30 and 84 years. A decreased ability to perform self-care tasks or to ambulate was frequently associated with pain due to degenerative arthritis secondary to muscle imbalance. The joints commonly involved were shoulder (15), knee (8), hip (5), ankle/foot (4) and wrist (2). Other causes of pain and disability included carpal tunnel syndrome (6), tension headache (5), fibrositis syndrome (3), bursitis/tendinitis (3) and thoracic outlet syndrome (1). All of the patients had scoliosis and many had back pain because of degenerative disc disease (15), spondylosis (8), sacroiliac joint pain (7) and lumbar spinal cord stenosis (3). Though unaccompanied by pain, increasing joint laxity and muscular contracture accounted for increasing disability in 23 patients. Fatigue was a frequent complaint (26) unexplained by anemia, electrolyte disturbance or hormonal dysfunction.

Perhaps most frightening to some polio survivors is the gradual or sometimes sudden onset of progressive weakness (20). In some cases the weakness was explained by radiculopathy (4), lumbar stenosis (3), compression neuropathy (7) or brachial plexitis (1). In these cases the weakness was accompanied by pain, numbness or other appropriate symptoms and signs. In others (5) the weakness was not associated with pain or any other symptoms except fasciculation or a sense of impeding cramp. The weakness was limited to muscle groups previously weakened by poliomyelitis. Alter and other authors have described late progression of weakness in postpolio patients though the cause or mechanism is unknown. Wiechers and Hubbell have studied postpolio patients with single-fiber electromyography, with findings consistent with defective neuromuscular transmission in reinnervated motor units.

Progressive resistive or strengthening exercises have not been helpful in cases of late progressive weakness. In fact, patients have been cautioned to avoid excessive or exhausting exercise. Swimming remains the best form of exercise for the conditioning effect while unloading painful or arthritic joints. Regardless of the cause of decreasing function, patients are encouraged to practice joint and energy conservation in their activities of daily living and in their work situations.

Stanley K. Yarnell, M.D.

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Sexuality and Disability

In the past, physically disabled persons were often seen as asexual—without sexual needs, desires or capabilities. Professionals avoided dealing with sexual dysfunction due to lack of training, personal discomfort and a feeling of futility about therapeutic attempts.

This negative stereotype is difficult to sustain in view of the growing literature and research on the subject. For example, we know from the studies of Bors and Comarr that 96% of men who are quadriplegic from cervical spinal cord injury are capable of having an erection and that more than 72% of these men can have intercourse. A recent study of stroke survivors indicates that 73% of the women and 88% of the men retain sexual desire following their disability, and 46% of the men retain the ability to achieve erection.

Today when a person suffers paralysis, amputation, arthritis, cardiopulmonary disease or other illness, modern sex education, counseling and therapy techniques are integrated into the rehabilitation plan to develop sexual capacities to the fullest possible extent.

The goal of sex education is to impart accurate information to all patients who wish to know about sexuality and the effects of disability. Classes, books and movies can be effective supplements to teaching positioning (arthritis, back pain, stroke), the management of incontinence (paraplegia, quadriplegia, ostomy), energy cost of intercourse (cardiopulmonary disease) and side effects of drugs (hypertension, multiple sclerosis).

Sexual counseling is additionally used for those with specific sexual conflicts or needs. Counseling may help with body image concerns (mastectomy, amputation, burns), to decrease performance anxiety, to dispel myths, to broaden attitudes regarding sexual options and to improve ability to communicate effectively about sexual issues. Social skills training is especially helpful for the congenitally disabled.

Sex therapy is needed by the relatively few disabled persons whose problems are not resolved by education and counseling. An intensive individualized program includes sensate-focus exercises most commonly for the treatment of erectile dysfunction, premature ejaculation or anorgasmia. It can also be used as a therapeutic trial before the insertion of a penile prosthesis (diabetes, nephropathy).

With the advent of these approaches, it has become clear that physical disability does not necessarily lead to sexual disability.

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Urinary Infection in a Neurogenic Bladder

Neurogenic bladder dysfunction can occur due to traumatic and other lesions of the spinal cord such as multiple sclerosis, tumors, diabetes mellitus, stroke and the like. The resulting bladder dysfunction causes disturbances in normal micturition. In many patients with such dysfunction, use of an indwelling catheter may be eliminated by intermittent catheterization, therapy with α-sympathetic blockers or transurethral surgical repair (or all three). Bacterial colonization or obvious urinary tract infection continues to be a common occurrence, particularly in patients who wear external collecting devices and a leg bag. Urinary tract infections are a major cause of mortality in patients with spinal cord injury and neurogenic bladders.

Diagnosing urinary tract infections by symptoms alone in patients with neurogenic bladders is unreliable. Lack of symptoms such as fever, chills, dysuria and flank pain, in spite of significant bacteriuria (greater than 100,000 per ml), continues to be common in most patients with spinal cord injury who have unobstructed voiding. In an unpublished study by Perkash and coworkers (1982), only 3% of 103 patients with spinal cord injury had symptoms, in spite of bacteria in a urine specimen numbering more than 100,000 per ml. Thus, symptoms per se are poorly correlated with significant bacteriuria in such patients. Due to this lack of clinical signs, bacteriuria poses a therapeutic dilemma in treatment and management. In addition, with complicating factors of perineal and drainage bag contamination, the question of colonization versus true tissue invasion arises. Quantitating urine pyuria has proved helpful for clinically determining urinary tract infection. Microscopic examination of urine sediment for the presence of leukocytes is a time-honored technique, but one that is poorly standardized and thus semiquantitative. Quantitating pyuria, however, is a simple and logical improvement of this technique. The usefulness of hemacytometer counting of uncentrifuged urine leukocytes in urine specimens of a general hospital's inpatients was reported in 1976. The presence of 10,000 or more leukocytes per ml of urine was correlated with the presence of a urinary tract infection. In another (unpublished) study, the presence of more than 10,000 leukocytes per ml of urine was highly predictive of the presence of bacteriuria in men with spinal cord injury.

As a result of our continued investigations to define and manage urinary tract infection in a neurogenic bladder, certain general guidelines have been developed. For patients being maintained on indwelling Foley catheter drainage, only symptomatic bacteriuria associated with fever and chills is treated; otherwise, no antimicrobial treatment or prophylaxis is recommended. Patients catheterized intermittently who remain asymptomatic despite significant bacteriuria are not generally treated. Due to regular, timed bladder emptying, bladder bacteriuria, if due to simple colonization, could be transient and thus flushed out at the next catheterization. However, if a patient has bacteriuria and symptoms of fever and chills, treatment is based on the urine culture-sensitivity report. Finally, patients receiving external condom drainage who have asymptomatic bacteriuria with fewer than 10,000 leukocytes per ml of urine may not require treatment if the bladder is draining adequately. This type of bacteriuria could be a contaminant from a patient's own perineum or drainage bag. Attention towards maintaining proper hygiene might be the only recourse for reducing or controlling the incidence of asymptomatic bacteriuria.

The recent development and use of noninvasive "markers" to define a site of infection and therefore direct the most effective type of treatment is now being studied. Surface blockers or specific antipilial antibodies available to prevent bacterial adhesion and colonization on the bladder mucosa may provide a lasting cure.

Inder Perkash, M.D.
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Electrodiagnosis in Brachial Plexus Injury

Following brachial plexus injury, electrodiagnostic changes are seen most commonly during needle electromyography. Changes in nerve conduction velocity studies are much less common because, one, plexus injuries most often produce axonal loss rather than demyelination and, two, there are many technical problems with brachial plexus nerve conduction studies.

The electromyographic examination must include the infraspinatus and supraspinatus, rhomboid, levator scapulae, serratus anterior and cervical paraspinal muscles to accurately assess the proximal extent of plexus injury.

Although changes in motor or sensory conduction velocities are not common in plexopathy, a reduction in amplitude of the motor or sensory evoked potential is common. Abnormalities of conduction or evoked-potential amplitude change may be most common in the musculocutaneous nerve. The role of F-wave studies is controversial, while the value of studies such as C-8 root stimulation remains to be determined.

An important issue in traumatic plexopathy—and one of the major uses of sensory conduction testing— is the attempt to differentiate between preganglionic and postganglionic lesions. With complete sensory loss in a given dermatome, a normal sensory nerve action potential suggests a preganglionic lesion (root avulsion) whereas an absent response suggests a postganglionic lesion if the study is done at least five days after the injury.

Recently the value of somatosensory evoked potentials in the electrodiagnosis of traumatic brachial plexopathy has been established. They seem to be particularly useful in differentiating preganglionic and postganglionic lesions. Three components of the somatosensory evoked potenials are used. N9, N13 and N20. N9 is thought to arise from the brachial plexus and its amplitude is diminished only by a postganglionic lesion. N13 arises in the cervical cord or brain stem, while N20 is a cortical potential. N20 and N13 amplitudes would be affected by either a preganglionic or a postganglionic lesion. Amplitude attenuation of greater than 40% compared with the opposite side is the critical value. A comparison of N9 and N13 amplitudes is used to delineate the degree of preganglionic involvement. If the N9 amplitude decrease is equal to or greater than that in N13, the lesion is totally postganglionic. N9 is normal and N13 is abnormal in pure preganglionic lesions. In mixed lesions N13 is more affected than N9 and the degree of both preganglionic and postganglionic involvement may be estimated from the values. The evaluation of the somatosensory evoked potential is felt to be the most accurate tool for addressing the issue of preganglionic and postganglionic involvement. Accurate assessment is critical because of recent advances in the surgical repair of postganglionic plexus lesions.

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Universal Contoured Cushions for Wheelchair-Bound Patients

The present-day conventional wheelchair provides little in the way of body support or prevention of soft tissue trauma for a person who has lost sensory feedback or motor function. A new wheelchair seat cushion designated as a Veterans Administration spinal injury orthosis for paraplegics (VASIO-P) has been developed that reduces the ischemia-producing forces and redistributes them to the more tolerant areas of the posterior thighs and lateral gluteal muscles. The cushion is made of foam materials and designed to stabilize the pelvis and promote spinal-pelvic alignment. Pressure measurements were done of 81 persons while seated on the cushion in their own wheelchair. The cushion was effective in reducing pressures to tolerate levels for 65 of them. The cushion was more effective (89% versus 57%) for persons without certain skeletal deformities (pelvic obliquity, bony resections). Of the respondents using the cushion, 83% reported that they preferred it to their previous cushions, with the most commonly cited reasons being improved posture, balance and comfort. This study has shown the cushion to be a preferred alternative to other commercially available wheelchair cushions.

Inder Perkash, M.D.

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Heterotopic Ossification in Cases of Head Injury

Heterotopic ossification is a frequent sequela of central nervous system injury. It is commonly encountered in cases of spinal cord injury, head injury, cerebrovascular accident and burns. Unlike myositis ossificans traumatica (the formation of calcification and heterotopic bone as a result of local trauma), neurogenic heterotopic ossification is not associated with local trauma. The incidence of heterotopic ossification in patients with a head injury has been reported to be between 11% and and 70%.

Factors such as length of coma, depth of coma, level of spasticity and duration of immobility apparently account for the discrepancy in incidence. There is a possibility that osseous trauma may be associated with an increased incidence of heterotopic ossification distal to the trauma site, but this may, in fact, be due to the extent of the original cerebral injury.

The onset of heterotopic ossification may be as early as two weeks postinjury and patients remain susceptible to its onset through the first nine months after injury. Triple-phase bone scan studies clearly show increased local vascularization in a site where heterotopic bone ultimately develops. Although the alkaline phosphatase level is raised in the presence of calcium deposition, the development of heterotopic ossification precedes the elevation of serum alkaline phosphatase. Conventional x-ray studies are normal in the earliest stages of developing ossification. The most consistently reliable diagnostic indicator is a bone scan that shows increased uptake; the earliest changes are shown by triple-phase bone scan studies.

Although the hip appears to be the most common site of heterotopic ossification formation, it occurs with almost equal frequency in the upper extremities and at both the elbow and the shoulder from craniocerebral injury.

In the phase of increased local blood flow, the involved extremity may present with swellng, localized and systemic temperature elevation and rubor. The differential diagnosis at this stage includes thrombophlebitis. Every effort should be made to preserve as much motion as possible in a joint that shows early heterotopic ossification and, thus, passive range of motion is essential. In the early phases, when joint mobility is threatened, manipulation may be considered. At the first sign of heterotopic ossification, etidronate disodium therapy should be initiated because in some 16% of cases of heterotopic ossification, joint ankylosis will develop. In some patients treated with etidronate disodium, heterotopic ossification will continue to develop and it appears that a dosage of 20 mg per kg of body weight and a longer period of treatment may be necessary.

Sheldon Berrol, M.D.

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Rehabilitation of Stroke Patients Who Have Associated Cardiac Disease

The potential for a combination of myocardial infarction and cerebrovascular accident, or stroke, to occur following a cardiac surgical procedure is well known. The rehabilitation of such patients with this combined problem must proceed with care so that the stroke rehabilitation program does not exceed a patient's exercise tolerance relative to the coexisting heart disease. This problem is illustrated by the fact that a hemiplegic patient who ambulates without bracing uses about 65% more energy in ambulating than does a normal person walking at the same speed. Similarly, a hemiplegic person uses up to 35% more energy in climbing stairs than does a normal person.

Recently a program has been designed for managing patients with combined cerebrovascular and cardiac diseases using principles of both stroke and cardiac rehabilitation.

This program proceeds in a stepwise fashion through steps 1 to 14 much as in a typical cardiac rehabilitation program. Although in the traditional cardiac program a patient advances one step a day, each step may take one or several days in a program for the combined disorder. The key to the combined program is careful control of energy expenditure varying from 1.12 METS (metabolic equivalent; 3.5 ml of oxygen per kilogram per minute) at step 1 to 9 METS at step 14. This planned energy expenditure is in keeping with standards for cardiac rehabilitation. Within the program as outlined, there are specific suggestions for physical and occupational therapy and ward activities.

Further specific guidelines include allowing a maximum heart rate of 110 a minute or less in the early steps and 120 a minute or less at step 14. Data for calculating maximal allowable heart rates by percent increase are also available as are further medical precautions such as ceasing activity with angina, and getting electrocardiograms and Holter monitor studies. As with routine cardiac rehabilitation, adequate warm-up and cool-down periods are necessary.

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Staged Treatment of Spasticity

Spasticity is present in central nervous system diseases such as stroke, spinal cord injury and multiple sclerosis.

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In patients with lifelong disability, the dangers of adverse effects and addiction are so significant that five stages of treatment have recently become established: (1) reassurance and education, (2) prevention and treatment of contributing causes, (3) physical therapy, (4) medication and (5) blocks and surgical procedures.

During the first stage, a physician needs to reassure and educate the patient and family about the following: spasticity retards muscle atrophy and decreases the chances of phlebitis occurring: an increase in spasticity is an invaluable diagnostic clue when patients cannot feel pain with the occurrence of lithiasis, decubiti, appendicitis or fractures; when spasticity is removed, patients may lose erections, bowel and bladder control, and may suffer further impairments in ambulation or transfers.

The second stage is that of amelioration of inflammation, infection, anxiety and agitation that may aggravate the spasticity. Support, relaxation and cognitive therapy are preferable to psychotropic drugs, many of which have hypotensive, anticholinergic, sedative or habituating side effects.

The third stage involves physical therapy (reducing contractures), functional training (moving the metatarsal heads off wheelchair pedals stops clonus) and physical modalities (heat at 38 °C[100 °F], ice to 15 °C [59 °F]).

Once the first three stages have been implemented, additional measures should be taken only when spasticity interferes with function or hygiene or produces significant discomfort.

The fourth stage involves medication. Baclofen, which inhibits reflexes in the spinal cord, is the first-line drug, except in patients who have a history of hallucinations or seizures. Dantrolene sodium, which has a direct effect on muscle, is the second-line drug; it occasionally produces a hepatotoxic reaction. Diazepam is the third drug. Its effectiveness is correlated in large measure with a sedative effect. It may produce urinary retention, respiratory depression and addiction. If an adequate response is not obtained with a single drug, two may be tried together. All three drugs taken simultaneously usually produce unacceptable side effects.

The fifth stage involves chemical neurolysis and surgical procedures. Motor point and nerve blocks are the simplest and safest methods of treating focal spasticity such as ankle clonus and adductor spasticity. Other ablative procedures are drastic and preclude any hope of future recovery.

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Nuclear Magnetic Resonance Spectroscopy for Diagnosis of McArdle's Disease

Muscle discomfort, pain and even muscle cramps are symptoms *occasionally* experienced by everyone following unaccustomed exercise. Because this is such a common experience, these symptoms frequently receive little attention in routine history taking and physical examination. In a healthy person, these symptoms only occur following strenuous exercise. Patients with a metabolic disorder that interferes with muscle energy supply mechanisms have pains and cramps with even moderate activity. Common diagnoses are laziness, malingering or psychosomatic illness. For example, patients who have McArdle's disease usually have symptoms from childhood, but this disorder is rarely diagnosed until the symptoms become severe, usually during the fourth or fifth decade. As children, if they try to "keep up with their peers" they experience pain and on occasion will have pigment in their urine. As adults, because of the muscle pain they are unable to continue at jobs that require a mild or moderate amount of physical activity for more than brief periods. By all traditional methods for physical examination, they appear healthy and normal, a fact that usually results in a diagnosis of malingering or psychosomatic illness. With aging, the altered muscle function becomes more obvious and a diagnosis may finally be made. In the meantime, a patient may even undergo unneeded laminectomy in the hope that limb "claudicatory" symptoms can be relieved.

McArdle's disease is diagnosed by electromyographic confirmation of electrical silence during muscle contracture, absence of ability to raise the serum lactate level with ischemic exercise, histochemical evidence of glycogen accumulation (glycogen storage disease) and biochemical assays to confirm the absence of phosphorylase activity on tissue taken at muscle biopsy. All of these methods are invasive to a minor or a major degree.

A new *noninvasive* method is now available for studying the energetics of muscle function. The technique is topical nuclear magnetic resonance spectroscopy (no relationship to nuclear magnetic resonance imaging). This technique is of proved value in confirming the diagnosis of McArdle's disease and, based on our recent experience, has potential for identifying carriers of this disorder. The procedure evaluates consumption and alteration of the various high-energy phosphagens noninvasively while muscle activity is occurring. Therefore, this technique has the potential to identify cases of other enzymatic disorders that relate to energetics of muscle function. Topically applied nuclear magnetic resonance will not replace the standard diagnostic procedures. However, it significantly expands the ability to noninvasively screen patients with signs and symptoms suggesting a metabolic disorder of muscle function. Although not yet widely available, it is an established tool in the evaluation of muscle disorders.

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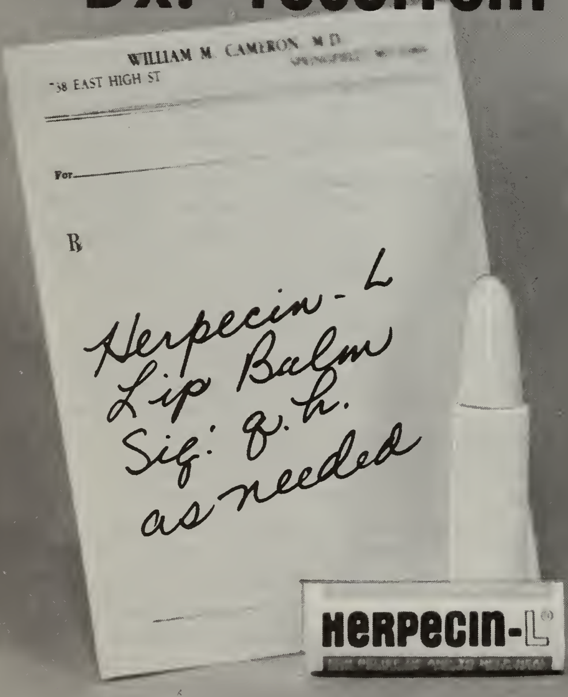

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Osteoporosis

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Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

Introduction

Osteoporosis is a major underlying cause of bone fractures in post-menopausal women and older persons in general. It is a condition in which bone mass decreases, causing bones to be more susceptible to fracture. A fall, blow, or lifting action that would not bruise or strain the average person can easily cause one or more bones to break in a person with severe osteoporosis.

Medical practitioners and patients alike are concerned with the optimum approach to the treatment and prevention of osteoporosis. The appropriate timing and proper use of agents, such as calcium, vitamin D, estrogens, and fluorides, as well as the role of exercise are issues that have generated major research efforts and considerable controversy.

In an effort to resolve some of the questions surrounding these issues, the National Institutes of Health convened a Consensus Development Conference on Osteoporosis on April 2-4, 1984. After a day and a half of presentations by experts in the field, a consensus panel including representatives of orthopaedics, endocrinology, gynecology, rheumatology, epidemiology, nutrition, biochemistry, family medicine, and the general public considered the evidence and agreed on answers to the following key questions:

- What is osteoporosis?
- What are the clinical features of osteoporosis, and how is it detected?
- Who is at risk for developing osteoporosis?
- What are the possible causes of osteoporosis?
- How can osteoporosis be prevented and treated?
- What are the directions for future research?

Panel's Conclusions

Osteoporosis is a major public health problem. Although all bones are affected, fractures of the spine, wrist, and hip are typical and most common. The risk of developing osteoporosis increases with age and is higher in women than in men and in whites than in blacks. Its cause appears to reside in the mechanisms underlying an accentuation of the normal loss of bone, which follows the menopause in women and occurs in all individuals with advancing age. There are no laboratory tests for defining individuals at risk or those with mild osteoporosis. The diagnosis of primary osteoporosis is established by documentation of reduced bone density or mass in a patient with a typical fracture syndrome after exclusion of known causes of excessive bone loss. Prevention of fracture in susceptible patients is the primary goal of intervention. Strategies include assuring estrogen replacement in postmenopausal women, adequate nutrition including an elemental calcium intake of 1,000-1,500 mg a day, and a program of modest weight-bearing exercise. There is great need for additional research on understanding the biology of human bone, defining individuals at special risk, and developing safe, effective, low-cost strategies for fracture prevention.

From the Office of Medical Application of Research, National Institutes of Health, Bethesda, Md.

Reprint requests to the Office of Medical Applications of Research, Room 216, National Institutes of Health, Bethesda, MD 20205 (Michael J. Bernstein).

1. What is osteoporosis?

Primary osteoporosis is an age-related disorder characterized by decreased bone mass and by increased susceptibility to fractures in the absence of other recognizable causes of bone loss.

Osteoporosis is a common condition affecting as many as 15-20 million individuals in the United States. About 1.3 million fractures attributable to osteoporosis occur annually in people age 45 and older. Among those who live to be age 90, 32 percent of women and 17 percent of men will suffer a hip fracture, most due to osteoporosis. The cost of osteoporosis in the United States has been estimated at $3.8 billion annually.

Bone is composed of a collagen-rich organic matrix impregnated with mineral—largely calcium and phosphate. Two major forms of bone exist. Compact cortical bone forms the external envelopes of the skeleton; trabecular or medullary bone forms plates that traverse the internal cavities of the skeleton. The proportions of cortical and trabecular bone vary at different sites. Vertebral bodies contain predominantly trabecular bone, while the proximal femur contains predominantly cortical bone. The responses of the two forms of bone to metabolic influences and their susceptibility to fracture differ.

Bone undergoes continuous remodeling (turnover) throughout life. Osteoclasts resorb bone in microscopic cavities; osteoblasts then reform the bone surfaces, filling the cavities. Normally, bone resorption and formation are linked closely in space, time, and degree. Mechanical and electrical forces, hormones, and local regulatory factors influence remodeling.

Peak bone mass is achieved at about 35 years of age for cortical bone and earlier for trabecular bone. Sex, race, nutrition, exercise, and overall health influence peak mass. Bone mass is approximately 30 percent higher in men than in women and approximately 10 percent higher in blacks than in whites. In each group, bone mass varies among individuals.

After reaching its peak, bone mass declines throughout life due to an imbalance in remodeling. Bones lose both mineral and organic matrix but retain their basic organization. In women, bone mass decreases rapidly for 3 to 7 years after menopause. Bone loss also is enhanced in a variety of diseases.

Women have more fractures than men, and whites have more fractures than blacks. Three factors determine the likelihood of fractures: first, the magnitude, direction, and duration of the applied force; second, the dissipation of that force by muscle contraction and soft tissue absorption; and finally, bone strength. Injuries are more frequent and energy dissipation diminishes with advancing age. Reduction in bone mass is the most important reason for the increased frequency of bone fractures in postmenopausal women and in the elderly.

Classifying primary osteoporosis into clinical, histological, or biochemical subsets may be useful from the standpoints of etiology, prevention, and treatment. There is clinical and histological evidence for different subsets. Vertebral fractures occur most frequently in women aged 55 to 75 with accelerated loss of trabecular bone. Hip fractures occur most frequently in older men and women who slowly have lost both cortical and trabecular mass. Bone biopsies from some individuals with primary osteoporosis show high turnover rates; biopsies from others show low or intermediate rates of turnover.

2. What are the clinical features of osteoporosis, and how is it detected?

The clinical manifestations of osteoporosis include fractures and their complications. Characteristically, fractures occur in the thoracic and lumbar vertebral bodies, the neck and intertrochanteric regions of the femur, and the distal radius. Osteoporotic individuals may fracture any bone more easily than their nonosteoporotic counterparts.

Vertebral compression fractures occur more frequently in women than in men, and typically affect T^8-L^3. These fractures may develop during routine activities, such as bending, lifting, or rising from a chair or bed. Immediate, severe, local back pain often results. Pain usually subsides within several months. Some individuals experience persistent pain due to altered spinal mechanics. In contrast, some vertebral fractures do not cause pain. Gradual asymptomatic vertebral compression may be detected only upon radiographic examination. Loss of body height and/or the development of kyphosis may be the only signs of multiple vertebral fractures. Discomfort, debility, and, rarely, pulmonary dysfunction may accompany thoracic shortening. Abdominal symptoms may include early satiety, bloating, and constipation.

Hip fractures are another important manifestation of osteoporosis. The affected population tends to be older and the sex distribution more even than is the case in vertebral fracture.

Acute complications—hospitalization, depression, and mechanical failure of the surgical procedure—are common. Most patients fail to recover normal activity, and mortality within 1 year approaches 20 percent. Distal radial fractures limit use of the extremity for 4 to 8 weeks, although long-term disability is uncommon. These fractures promote fear of loss of independent living, fear of additional falls and fractures, and depression.

Detection of low skeletal mass and/or a fracture after minor trauma should alert the physician to the presence of metabolic bone disease. The physician should evaluate further to exclude osteomalacia, hyperparathyroidism, hyperthyroidism, multiple myeloma, metastatic disease, syndromes of glucocorticoid excess, and other causes of secondary osteoporosis. No blood or urine test establishes specifically the diagnosis of primary osteoporosis, but such tests may exclude secondary causes.

Several noninvasive methods are available to evaluate bone density. These vary widely in cost, availability, and radiation dose. Standard radiographs of the spine are most widely available. Roentgenograms are, however, insensitive indicators of bone loss, since bone density must be decreased by at least 20 to 30 percent before the reduction can be appreciated. Characteristic abnormalities on standard roentgenograms are sufficient for establishing the diagnosis of osteoporosis if secondary causes are excluded clinically or radiographically. If the spine film is not diagnostic but clinical suspicion is high, a variety of other procedures may be indicated. These include radiogrammetry for measurement of cortical thickness, photodensitometry, the Singh Index of femoral trabecular pattern, single and dual photon absorptiometry, neutron activation, Compton scattering, and single and dual energy computed tomography. Use of these techniques will depend on their availability, cost, and further studies of their discriminatory capabilities and sensitivity.

With histomorphometry, usually performed on a bone biopsy from the iliac crest, bone mass can be evaluated and osteomalacia and certain forms of secondary osteoporosis excluded. Bone biopsy is safe but requires specialized equipment and expert analysis that are not widely available.

3. Who is at risk for developing osteoporosis?

The correlation of osteoporosis with the following factors is well documented. Bone mass declines with age in all people and is related to sex, race, menopause, and body weight-for-height.

Women are at higher risk than men in that they have less bone mass and, for several years following natural or induced menopause, the rate of bone mass decline is accelerated. Early menopause is one of the strongest predictors for the development of osteoporosis. White women are at much higher risk than black women, and white men are at higher risk than black men. Women who are underweight also have osteoporosis more often than overweight women. Cigarette smoking may be an additional predictor of risk. Calcium deficiency has been implicated in the pathogenesis of this disease.

Immobilization and prolonged bed rest produce rapid bone loss, while exercise involving weight bearing has been shown both to reduce bone loss and to increase bone mass. The optimal type and amount of physical activity that will prevent osteoporosis have not been established. Exercise sufficient to induce amenorrhea in young women may lead to decreased bone mass.

The relationship of osteoporosis to hereditary and dietary factors, such as alcohol, vitamins A and C, magnesium, and protein, is less firmly established. Some of these factors may act indirectly through their effect on calcium metabolism or body weight.

4. What are the possible causes of osteoporosis?

Because primary osteoporosis is characterized by decreased bone mass, the causes of the disorder must be sought among the factors that determine the quantity and quality of bone, including the magnitude of maximum bone mass at maturity and the rate of bone loss with aging.

Complex cellular, physiologic, and metabolic factors may underlie the pathogenesis of osteoporosis. Discrete cell types, anatomically and functionally connected, are continually renewed and maintain the complex skeletal tissue. Several systemic hormones and an increasingly recognized number of local (paracrine) factors regulate bone cell activity. Diet, as well as intestinal and renal function, influences mineral ion homeostasis needed to maintain the skeleton. The formation and resorption of bone and their coupling also are modified by external physical forces such as those generated by body weight and exercise.

Osteoporosis is histologically, biochemically, and kinetically heterogeneous; rapid bone turnover or reduced rates of bone formation have been documented in patients with primary osteoporosis. Multiple etiologies would not be surprising, considering the complex factors regulating normal bone metabolism. Among the many possible etiologies of primary osteoporosis, current data point to two probable causes: deficiency of estrogen and deficiency of calcium. Rapid bone loss often accompanies menopause, and premature osteoporosis follows bilateral oophorectomy. Estrogen replacement prevents bone loss in both conditions. The following observations support a causal relationship between calcium deficiency and osteoporosis: Calcium deficiency in experimental animals causes osteoporosis; a low calcium intake is common among the elderly in the United States; and calcium supplementation reduces bone loss.

5. How can osteoporosis be prevented and treated?

Physicians must emphasize measures that retard or halt the progress of osteoporosis before irreversible structural defects occur. The mainstays of prevention and management of osteoporosis are estrogen and calcium; exercise and nutrition may be important adjuncts.

Estrogen replacement therapy is highly effective for preventing osteoporosis in women. Estrogen reduces bone resorption and retards or halts postmenopausal bone loss. Case-controlled studies have shown a substantial reduction in hip and wrist fractures in women whose estrogen replacement was begun within a few years of menopause. Studies also suggest that estrogen reduces the rate of vertebral fractures. Even when started as late as 6 years after menopause, estrogen prevents further loss of bone mass but does not restore it to premenopausal levels. Oral estrogen protects at low doses, such as 0.625 mg of conjugated equine estrogen, (25 micrograms of mestranol and 2 mg of estradiol valcrate daily exemplify other protective regimens reviewed by the panel).

All of the above data on efficacy are based almost exclusively on studies in white women. Therefore, the following recommendations on therapy for osteoporosis pertain to that group. Cyclic estrogen therapy should be given to women whose ovaries are removed before age 50 in whom there are no specific contraindications. Women who have had a natural menopause also should be considered for cyclic estrogen replacement if they have no contraindications and if they understand the risks and agree to regular medical evaluations. The duration of estrogen therapy need not be limited. There is no convincing evidence that initiating estrogen therapy in elderly women will prevent osteoporosis. The decision to treat women of other racial backgrounds should be determined on a case-by-case basis.

Estrogen-associated endometrial cancer is usually manifested at an early stage and is rarely fatal when managed appropriately. The bulk of evidence indicates that estrogen use is not associated with an increased risk of breast cancer. Adding a progestogen probably reduces the risk of endometrial cancer, but there is little information about the safety of long-term combined estrogen and progestogen treatment in postmenopausal women. Younger patients receiving progestogens in oral contraceptives experienced an increased risk of hypertension and cardiovascular disease. Some progestogens may blunt or eliminate the favorable effects of estrogen on lipoproteins.

Until more data on risks and benefits are available, physicians and patients may prefer to reserve estrogen (with or without progestogen) therapy for conditions that confer a high risk of osteoporosis, such as the occurrence of premature menopause.

The usual daily intake of elemental calcium in the United States, 450 mg to 550 mg, falls well below the National Research Council's (NRC) recommended dietary allowance (RDA) of 800 mg; the RDA is designed to meet the needs of approximately 95 percent or more of the population. Calcium metabolic balance studies indicate a daily requirement of about 1,000 mg of calcium for premenopausal and estrogen-treated women. Postmenopausal women who are not treated with estrogen require about 1,500 mg daily for calcium balance. Therefore, the RDA for calcium is evidently too low, particularly for postmenopausal women and may well be too low in elderly men. In some studies, high dietary calcium suppresses age-related bone loss and reduces the fracture rate in patients with osteoporosis. It seems likely that an increase in calcium intake to 1,000 to 1,500 mg a day beginning well before the menopause will reduce the incidence of osteoporosis in postmenopausal women. Increased calcium intake may prevent age-related bone loss in men as well.

The major sources of calcium in the U.S. diet are milk and dairy products. Each 8 ounce glass (240 ml) of milk contains 275-300 mg calcium. Skim or low fat milk is prefered to minimize fat intake. For those unable to take 1,000 to 1,500 mg calcium by diet, supplementation with calcium tablets is recommended, with special attention to their elemental calcium content.

Levels of calcium intake greater than those recommended herein could cause urinary tract stones in susceptible people. Anyone with a history of kidney stones should only undertake calcium supplementation with the guidance of a physician.

Normal levels of vitamin D are required for optimal calcium absorption. The requirement for vitamin D increases with age. Persons who do not receive adequate daily sunlight exposure, such as those confined to home or to a nursing facility, are at special risk for vitamin D deficiency. Vitamin D has dangerous effects at high doses. Although the toxic dose varies among individuals, toxicity has occurred at levels as low as 2,000-5,000 international units [I.U.] daily. No one should consume more than 15 to 20 micrograms (600 to 800 units, twice the daily RDA) without a doctor's recommendation.

Inactivity leads to bone loss. Some recent studies suggest that weight-bearing exercise may reduce bone loss. Modest weight-bearing exercise, such as walking, is recommended.

Several agents and modalities of treatment are currently under investigation, but their efficacy and/or safety have not been established. These include sodium fluoride, calcitriol, calcitonin, weakly androgenic anabolic steroids, thiazides, bisphosphonates, the 1-34 fragment of parathyroid and "ADFR," a complex system of several drugs. Sodium fluoride, in association with a high calcium intake, may have a role to play in patients afflicted with severe osteoporosis, but its efficacy and safety are unproven; prospective studies are now under way.

Strategies to prevent falls are important in elderly patients who may fall frequently for a variety of reasons, such as from effects of drugs. Specific environmental interventions can minimize home hazards that increase the chances of falling.

Physicians treating fractures in osteoporotic patients should recognize the benefits of rapid return to function and avoidance of prolonged immobilization.

6. What are the directions for future research?

Future research in osteoporosis should approach the currently unanswered basic research questions concerning the development and maintenance of bone as a tissue. At the same time, there is great need for clinical and epidemiological research to further explore and extend the current potential for practical prevention and treatment of the disease. A deeper knowledge of factors controlling bone cell activity and regulation of bone mineral and matrix formation and remodeling should contribute ultimately to our understanding of the etiology of osteoporosis. This understanding will permit a more rational choice and evaluation of therapies, even as current treatments are evaluated clinically.

The panel recommends:

1. Observational and epidemiological studies to determine the impact of multiple demographic and behavioral factors on bone mass and fracture frequency. Such studies could be conducted by appropriate additions to existing population-based studies.
2. Clinical studies to determine whether the observed age, sex, and skeletal distribution differences in osteoporosis reflect different mechanisms and predict different responses to intervention.
3. Studies to develop accurate, safe, inexpensive methods for determining the level of risk for osteoporosis in an individual, to establish early diagnosis, and to assess the clinical course of the disease.
4. Studies to develop safe, effective, low-cost strategies which might be applicable to populations at large for maximizing peak bone mass, minimizing bone loss, and preventing fractures.
5. Studies to determine the optimal regimen of gonadal hormones for prevention of bone loss and fracture.
6. Studies to elucidate further the mechanisms of bone growth and remodeling, their local and systemic regulation, and their alteration in osteoporosis.
7. Studies to understand alterations in the structure and biomechanical properties of bone in osteoporosis and the relationship of these alterations to the mechanisms and managment of fractures.

The Conference was sponsored by the following: National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, Lester B. Salans, M.D., Director; Office of Medical Applications of Research, J. Richard Crout, M.D., Director.

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Chronic studies in rats and monkeys have shown mild renal toxicity with papillary edema and necrosis. Renal papillary necrosis has rarely been shown in humans treated with *Motrin* Tablets.

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Fluid retention and edema have been associated with *Motrin* Tablets; use with caution in patients with a history of cardiac decompensation or hypertension. In patients with renal impairment, reduced dosage may be necessary. Prospective studies of *Motrin* Tablets safety in patients with chronic renal failure have not been done.

Motrin Tablets can inhibit **platelet aggregation** and prolong bleeding time. Use with caution in persons with intrinsic coagulation defects and on anticoagulant therapy.

Patients should report signs or symptoms of **gastrointestinal ulceration** or bleeding, skin rash, weight gain, or edema.

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As with other nonsteroidal anti-inflammatory drugs, borderline elevations of liver tests may occur in up to 15% of patients. These abnormalities may progress, may remain essentially unchanged, or may be transient with continued therapy. Meaningful elevations of SGPT or SGOT (AST) occurred in controlled clinical trials in less than 1% of patients. Severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported with ibuprofen as with other nonsteroidal anti-inflammatory drugs. If liver disease develops or if systemic manifestations occur (e.g. eosinophilia, rash, etc.), *Motrin* should be discontinued.

Drug interactions. *Aspirin:* used concomitantly may decrease *Motrin* blood levels.

Coumarin: bleeding has been reported in patients taking *Motrin* and coumarin.

Pregnancy and nursing mothers: *Motrin* should not be taken during pregnancy or by nursing mothers.

Adverse Reactions: The most frequent type of adverse reaction occurring with *Motrin* is gastrointestinal of which one or more occurred in 4% to 16% of the patients.

Incidence Greater than 1% (but less than 3%)—Probable Causal Relationship

Gastrointestinal: Nausea,* epigastric pain,* heartburn,* diarrhea, abdominal distress, nausea and vomiting, indigestion, constipation, abdominal cramps or pain, fullness of GI tract (bloating and flatulence); **Central Nervous System:** Dizziness,* headache, nervousness; **Dermatologic:** Rash* (including maculopapular type), pruritus; **Special Senses:** Tinnitus; **Metabolic/Endocrine:** Decreased appetite; **Cardiovascular:** Edema, fluid retention (generally responds promptly to drug discontinuation; see PRECAUTIONS).

Incidence less than 1%—Probable Causal Relationship**

Gastrointestinal: Gastric or duodenal ulcer with bleeding and/or perforation, gastrointestinal hemorrhage, melena, gastritis, hepatitis, jaundice, abnormal liver function tests; **Central Nervous System:** Depression, insomnia, confusion, emotional lability, somnolence, aseptic meningitis with fever and coma; **Dermatologic:** Vesiculobullous eruptions, urticaria, erythema multiforme, Stevens-Johnson syndrome, alopecia; **Special Senses:** Hearing loss, amblyopia (blurred and/or diminished vision, scotomata, and/or changes in color vision) (see PRECAUTIONS); **Hematologic:** Neutropenia, agranulocytosis, aplastic anemia, hemolytic anemia (sometimes Coombs positive), thrombocytopenia with or without purpura, eosinophilia, decreases in hemoglobin and hematocrit; **Cardiovascular:** Congestive heart failure in patients with marginal cardiac function, elevated blood pressure, palpitations; **Allergic:** Syndrome of abdominal pain, fever, chills, nausea and vomiting; anaphylaxis; bronchospasm (see CONTRAINDICATIONS); **Renal:** Acute renal failure in patients with pre-existing significantly impaired renal function, decreased creatinine clearance, polyuria, azotemia, cystitis, hematuria; **Miscellaneous:** Dry eyes and mouth, gingival ulcer, rhinitis.

Incidence less than 1%—Causal Relationship Unknown**

Gastrointestinal: Pancreatitis; **Central Nervous System:** Paresthesias, hallucinations, dream abnormalities, pseudotumor cerebri; **Dermatologic:** Toxic epidermal necrolysis, photoallergic skin reactions; **Special Senses:** Conjunctivitis, diplopia, optic neuritis; **Hematologic:** Bleeding episodes (e.g., epistaxis, menorrhagia); **Metabolic/Endocrine:** Gynecomastia, hypoglycemic reaction; **Cardiovascular:** Arrhythmias (sinus tachycardia, sinus bradycardia); **Allergic:** Serum sickness, lupus erythematosus syndrome, Henoch-Schönlein vasculitis; **Renal:** Renal papillary necrosis.

*Reactions occurring in 3% to 9% of patients treated with *Motrin.* (Those reactions occurring in less than 3% of the patients are unmarked.)

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Overdosage: In cases of acute overdosage, the stomach should be emptied. The drug is acidic and excreted in the urine so alkaline diuresis may be beneficial.

Dosage and Administration: Rheumatoid arthritis and osteoarthritis. Suggested dosage is 300, 400, or 600 mg t.i.d. or q.i.d. Do not exceed 2400 mg per day. Mild to moderate pain: 400 mg every 4 to 6 hours as necessary.

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Connecticut Physician Assistants: Update

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Introduction

With the graduation of the Class of 1984 from the Yale University School of Medicine's Physician Associate Program, a full 11 years will have passed since the first physician assistants (PA) trained in Connecticut were graduated. During that time, the number of PAs in the state has continued to increase, statewide trends in their practice have become evident, and recent changes have occurred. Survey results of all Connecticut based PAs and their physician employers highlights this development as well as the current status of these health practitioners in the state (See Table 1).

Table 1
P.A. CHARACTERISTICS (N = 118)

Average Age	32 years old (range 23-54)
Sex	Male–53% Female–47%
Prior Experience	Medical Tech–36 Medic–22 EMT–18 Nurse Aide–16 R.N.–6
Prior Education*	68% have at least four years college
Average Time In Practice	Five years (range 1–10 years)
Practice Settings	Hospitals–68% Clinics & Private Offices–19% Other (Industry, Nursing Homes, etc.)–13%

*Based on national survey done in 1981

Soon after the first PA program began at Duke University, Durham, North Carolina in 1965, members of this new health profession, commonly referred to as a physician assistant (PA), began to appear in Connecticut. Of the 266 graduates of Yale's PA program, many have chosen to remain in the state, bolstering the number of PAs practicing here. While a total of 16,000 formally trained PAs are in practice nationwide at this time, about 200 PAs work in Connecticut. This number includes not only Yale's graduates, but also graduates of the 55 other approved programs nationwide. The PA works, by law, as a dependent practitioner under the direction and supervision of a physician. The depth of their clinical experience allows them to help in making decisions regarding common patient problems, including diagnosis and treatment. PAs are being used statewide in a variety of clinical settings to increase and expand the health care services available to the general population. Their tasks vary with those practice settings, but include a number common to each setting (See Table 2).

Table 2
TYPICAL PA TASKS

TYPICAL PA TASKS
History and Physical Examinations
Order and Review Laboratory Data
Suture Uncomplicated Lacerations
Perform Minor Surgery
Assist in Operating Room
Refer Patients to Consultants
Dictate Discharge Summaries
Well Baby Care
Floor Procedures (LPs, Catherizations, Central-Lines, Chest Tubes)
Assess and Monitor Patients in the ICU
Initial Emergency Service Evaluations of Ill and Injured Patients
Provide Full-Time In-House Coverage

Education

The Yale PA Program exemplifies the essentials of an educational program for physician assistants. As noted in the PA Program catalog "PAs are distinguished from other health professionals by the extent to which they are given decision making authority regarding patient care,

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diagnosis and treatment, and by the depth of their clinical experience. Consequently, the education of physician assistants is of the medical model employed in physician education."

In regards to qualifications for admission to the Yale P.A. Program, there are two major items. The first of these is a baccalaureate degree. This degree may be in any area and serves as evidence of the candidate's ability to do college level work. While this requirement may be waived by the Director of Admissions, that occurs only under the most unusual circumstances when an individual has extensive health care experience. Over the last four years, the Yale program has taken only three people without a baccalaureate degree, and these were all nurses who had at least a nursing degree.

The second requirement is previous health care experience. While there is no absolute minimum, the majority of students had two or more years of direct patient care prior to applying to the Yale program. The type of experience is extremely varied and includes nurses, physical therapists, nurses aides, respiratory therapists and EMTS.

In support of the candidate's application, the Program requires transcripts from all schools, SAT scores, and three letters of reference—from an employer, a professor, and a personal acquaintance.

The Program receives approximately 150 applications per year. From this group, a class of the twenty-four most qualified applicants is selected.

The program is 24 months long. The first nine months are devoted to course work in basic sciences and medical pathophysiology taught by the Medical School Staff. During the next 15 months, the clinical phase, each student takes 10 five-week clerkships in different medical settings in order to acquire broad exposure to primary, surgical, and emergency care. Upon completion of the Program, a certificate is given from the Yale University School of Medicine acknowledging that the graduate has met all the requirements to practice as a physician assistant.

Further proof of competancy is demonstrated by passing a National Certification Examination administered by the National Board of Medical Examiners. This exam, as well as the entire recertification process, is overseen by the National Commission on Certification of Physician Assistants. This Commission is made up of representatives from many areas of organized medicine to include the AMA, ACS, AAFP and the ANA as well as the public audience.

Legislation

When the Yale PA Program opened its doors in 1970, the only reference to PAs in the state medical practice act was that the act " . . . shall not apply to any person rendering service as a physician's trained assistant if such service is rendered under the supervision, control and responsibility of a licensed physician." This law allowed flexibility and encouraged innovation in the health care field by codifying the authority of physicians to delegate medical tasks. The current legislation, which went into effect October 1, 1980, defines a physician assistant as "a skilled individual who is qualified by academic and practical training to provide patient services under the supervision, control, responsibility and direction of a licensed physician."

The law further defines the term "supervision" and sets the minimum qualifications for a person who represents himself as a PA. They include: graduation from a PA Program approved by the AMA; and within two years of that graduation, passage of the certifying examination administered by the National Commission on Certification of PAs. Although the law, when passed, provided for a degree of "grandfathering," those stipulations expired on December 31, 1981. One notable absence from the current law, which is present in the laws of 15 other states, is a provision for PAs to prescribe certain medications on an outpatient basis. In Connecticut, within institutions, PAs may write for medications, as well as all other orders, based on the individual institution's bylaws.

Practice Setting

A recent survey of state PAs and their employing physicians revealed that the majority of physician assistants are located in five practice setting types. Surgery (and its subspecialties) is the most frequent setting as noted by 23% of the survey respondents. Internal Medicine and Emergency Medicine are the next most frequent, each accounting for 20%. Family practice and pediatrics/neonatology closely follow at 15% and 14% respectively.

Contributing to the frequent use of PAs in Surgery is the presence in the state of a postgraduate training program for PAs in this specialty. The PA Surgical Residency Program, conducted jointly by Norwalk Hospital and the Yale University School of Medicine, is an intensive 12 month training period. It is designed to enhance the surgical capabilities and skills of selected graduate PAs whose careers are focused on the surgical field. Using the resources of both Norwalk and Yale provide a stimulating learning environment in which graduates qualify to serve as surgeon extenders in the capacity of surgical housestaff, functioning at the highest level in pre, intra, and postoperative care of the surgical patient. The PA residents perform admission history and physical exams, evaluate laboratory data, and write pre and postoperative orders at the direction of the attending surgeon. They develop expertise as first assistants in the operating room and actively help to manage the patient postoperatively.

Similar programs exist for PAs as pediatric housestaff at both Norwalk Hospital and Mt. Sinai Hospital in Hartford.

Norwalk Hospital's Pediatric Residency Program is a one year course designed to assist the development of cognitive and technical skills and the achievement of sound medical judgment for PAs interested in pediatrics. The curriculum, according to the brochure, " ... concentrates heavily on areas only surveyed in basic PA training and prepares the PA for major responsibilities participating with the pediatrician in the management of the patient." This program is also conducted in conjunction with the Yale University School of Medicine. Two months of the year are spent at Yale-New Haven Hospital in the specialty clinic and floor areas.

The Mt. Sinai Hospital – University of Hartford Program offers a Master's Degree in Pediatrics and Human Services. Similar in purpose to Norwalk's program, upon completion the PA would " ... under a physician's supervision, be able to evaluate and manage inpatient pediatric cases, provide pediatric care in an ambulatory setting, assess a normal newborn and identify and treat a sick newborn, intervene appropriately in a pediatric emergency, and provide a source of information and support to the child's family" (from promotional material).

With these three residency program, it is not surprising that the major practice setting for PAs in the state continues to be the hospital, as was noted by 68% of the respondents to this survey. As community physicians have begun to realize how beneficial PAs have been in the care of their hospitalized patients, a trend has begun towards outpatient, office based practice. The current distribution, with PAs located primarily in cities served by hospitals, will in all likelihood change significantly in the coming years (See Figure 1).

Physician Attitudes

A testimony to the degree of physician acceptance PAs have is illustrated by the results of a survey of physicians who employ PAs. Forty-five physicians responded to the survey. Of those, one-third were internists, 11% were in Emergency Medicine, and 8% were surgeons. The remainder were representative of the full variety of specialties. Two-thirds of the physicians responding supervised one or two PAs. The remaining third noted the responsibility for three to eight PAs. This latter ratio represents PA staff in hospitals being administratively responsible to either a single medical director or department chairman, but being clinically supervised by a variety of other attending physicians.

Physicians responding indicated that there were many advantages in employing a PA. Waiting time for patients was decreased according to two-thirds of the respondents. Assistance in the care of hospital patients was a definite plus, particularly when housestaff was not available or was small in number. Spending more time with a chronically ill patient and providing good primary care were mentioned by several respondents. Cost effectiveness was emphasized, and there was an increase in the number of patients seen. These respondents felt so strongly about the benefits of employing a PA, that 96% would recommend to their colleagues that they consider hiring a PA. They noted that they would certainly replace their PA if he/she were to leave the practice.

Professional Liability

The question of malpractice frequently arises among individuals seeking information regarding the profession. Since PAs share legal, ethical and moral responsibility for patients' care with their supervising physician, they normally carry malpractice insurance. This insurance is available to them as riders to the malpractice policies of employing physicians, or through the institutions were they work. Such insurance is also available on an individual basis.

However, this malpractice insurance is seldom utilized. With more than 12,000 MD/PA team practices in

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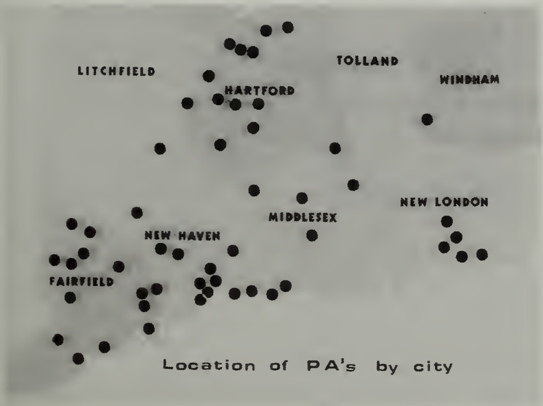
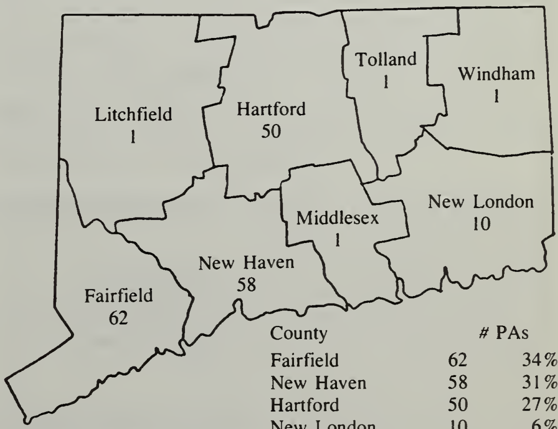


Location of PA's by city



County	# PAs	
Fairfield	62	34%
New Haven	58	31%
Hartford	50	27%
New London	10	6%
Litchfield	1	0.5%
Middlesex	1	0.5%
Tolland	1	0.5%
Windham	1	0.5%

this country, existing data strongly suggests that increased patient rapport, greater patient education, more comprehensive care and improved compliance actually reduce a physician's risk of malpractice litigation. In fact, in an article reporting on the fourth annual meeting of physician assistants, B.J. Anderson (A.M.A. assistant general counsel) stated that as a result of decreased waiting time and increased continuity of professional care " . . . I feel PAs probably hold the potential for being one of the best malpractice tools available at the present time."[1] That reduced liability will continue as long as the employing physician understands the PA's role and delegates responsibly.

Summary

PA's have become an increasingly significant part of the health care team in Connecticut. Their background and formal training, combined with the requisite physician supervision, permit them to help provide a high quality of medical care. At the same time, with their lower educational costs and salaries (average starting salary for PAs is $22-25,000), PA's can provide this care at a lower cost to the system.

The use of PA's, both within the institutional setting as well as increasingly in the private practice arena, continues to serve a very real need in the delivery of health care in this state. Included among the advantages of using PAs are decreased patient waiting time, more time with each patient, increased accessibility to health care, better in-house coverage and operating room assistance of a consistently high quality nature. In addition, based on the tasks that PAs do, physicians are afforded more time for both their sicker, more complicated patients, and for themselves as well.

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Freestanding Emergency Medical Care Centers

AMA BOARD OF TRUSTEES

At the 1981 Interim Meeting, the House of Delegates referred Resolutions 27 and 64 to the Board of Trustees who assigned them to the Commission on Emergency Medical Services for study and comment. Resolution 27 requests the AMA to establish an Ad Hoc Committee to study freestanding emergency care centers and Resolution 64 asks the AMA to define a true emergency medical center and establish criteria for its operation. Resolution 42, adopted by the House of Delegates at the 1982 Interim Meeting, called for submission of the study on freestanding emergency medical care centers for consideration at the 1983 Annual Meeting of the House of Delegates. In response to these resolutions, this report contains information on freestanding emergency centers and proposes initial criteria for their operation. This material is a result of the review conducted by the Commission's Task Force on Freestanding Emergency Centers.

Background

Freestanding "emergency" medical centers are known under several other names, such as emergicenter, emergency care clinic, minor emergency center, urgent treatment center, and freestanding emergency department. Such centers are a relatively new type of health care facility that has experienced rapid growth in the past decade. The first center was established in Delaware in 1975 and figures provided by the American College of Emergency Physicians and the American Hospital Association in 1982 indicate that there are, conservatively, more than 350 in operation today, and that the number of these centers is growing rapidly.

There are as yet no uniformly accepted criteria and guidelines for the establishment and operation of freestanding emergency centers. The comprehensiveness of emergency services provided, the mix of primary care services with emergency care, ownership, institutional affiliations, staffing, and method of financing vary significantly. In the absence of uniform criteria, efforts to determine the actual number of these clinics or to evaluate their capability of providing care in actual emergencies are extremely limited.

Two types of freestanding emergency centers have been identified: independent centers and hospital or hospital associated centers. The independent centers are generally regarded as physicians' offices and are treated as such for purposes of licensure, certificate of need requirements and third party reimbursement. On the other hand, the hospital sponsored or associated centers may be covered under a hospital license, subject to certificate of need requirements, and may be reimbursed as an institutional service by third party payors. Private insurance and self pay are the principal sources of reimbursement for these centers with Medicare, Medicaid, and Workmen's Compensation making up a rather small proportion of the remaining sources.

It is estimated that half of the treatment now provided in hospital emergency departments could be provided in physicians' offices. However, it is alleged that some health insurance carriers continue the practice of covering treatment in the hospital emergency department, but deny coverage of the same treatment in physicians' offices. Such practices by insurance carriers, according to the Commission, tend to limit patient choice and may increase expenditures, interfere with the continuity of care, and possibly burden hospital emergency departments. The Commission continues to study these problems of equitable reimbursement.

The Commission on Emergency Medical Services is concerned that the use of the term "emergency" in the title or description of a medical practice or a hospital center to encourage patient visits during "off-hours" without maintaining specific emergency capabilities is not in the public interest since needed critical emergency services may be delayed.

It is the patient who first decides what constitutes an "emergency" regardless of whether the physical or mental condition is of an urgent, life or limb threatening nature. Emergency care is for the patients' benefit and they have the right to expect that an emergency facility

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EDITOR'S NOTE: This is a report of the AMA Board of Trustees to the House of Delegates at its Annual Meeting, June, 1983.

will provide prompt and adequate medical evaluation and treatment of both acute and non-critical "emergencies." The Commission on Emergency Medical Services firmly believes the optimal provision of emergency care requires prompt physical access to the immediate resources of the hospital and that a freestanding emergency center without such access may delay definitive care of critical emergencies. However, it recognizes such a position does not respond to the House of Delegates request to define and develop criteria for the operation of these clinics, nor does it address the concern over possible misrepresentation by some clinics already in existence or being established.

Accordingly, the Commission has undertaken the initial development of operational criteria for freestanding emergency centers. The Commission emphasizes that these criteria are intended only to apply to emergency centers and not to affect the development of "convenience" or "access" clinics that are the equivalent of physicians' offices.

FREESTANDING EMERGENCY MEDICAL CARE CENTERS

Operational Criteria—Initial

In this section, the Commission on Emergency Medical Services proposes initial criteria to aid in determining whether a practice can truly offer a full range of emergency medical services.

The Commission does not believe there will be many freestanding "emergency" centers that will meet the criteria for true emergency care. However, it does believe the following initial criteria are sufficient to identify those centers that may be involved in the regular care of patients with critical emergencies.

1. *Hours of Operation*

Freestanding emergency medical care centers should be operational 24 hours a day, 7 days a week, 365 days a year to assure continuous public access.

2. *Staffing and Medical Direction*

A. There should be qualified physician(s), registered professional nurses, and other personnel trained in emergency care on duty with other ancillary personnel as needed for the function of the freestanding emergency medical care center.

B. Staff should have special competence in the diagnosis and immediate stabilization of patients with acute emergencies.

C. There should be a physician medical director of the center responsible for medical policies and staff qualifications.

D. A qualified physician(s) and other personnel trained in emergency care should be present within the center during all hours of operation.

3. *Relationship to the Emergency Medical Services System*

The freestanding emergency medical care center should be integrated into the local emergency medical services (EMS) system, where one exists, with its role and functions clearly identified in the local EMS plan and coordinated with other emergency facilities in the area.

To determine the role of a freestanding emergency medical care center in the local EMS system, consideration should be given to the time and distance from the center to the nearest appropriate hospital(s) identified in the EMS plan. Triage of ambulance patients to and from the freestanding emergency medical care centers should be under the "medical control" of the EMS system. In this context medical control means the prearranged physician direction and supervision of personnel, facilities, and equipment for the effective and coordinated provision of medical services to a specified area under emergency conditions.

4. *Ancillary Services and Equipment*

The freestanding emergency medical care center should have at least the following:

A. Laboratory on premises, with at least the following capabilities—CBC, UA, electrolytes, blood sugar, arterial blood gases, pregnancy test.

B. X-ray with on-premises processing with specialty review of diagnosis.

C. EKG—12 lead—with specialty review of diagnosis.

D. Monitor/Defibrillator—stationary or portable.

E. Monitor/Defibrillator—portable for transport and backup.

F. Crash cart with full advanced cardiac life support capabilities and necessary intraveneous fluids.

G. Appropriate trays and equipment for: accessing the airway, pericardiocentesis, needle thoracostomy, transvenous or transthoracic pacemaker, venous access, gastric lavage.

H. Oxygen

I. Suction

J. Pneumatic anti-shock trousers

K. Dedicated telephone line to the closest appropriate hospital emergency department and/or 2 way communication with the EMS medical control system.

5. *Protocols*

The freestanding emergency medical care center should have written protocols for the stabilization and transportation of patients requiring hospitalization or other more definitive care unavailable in the center.

6. *Private Physician Referrals*

The freestanding emergency medical care center should have adequate arrangements for patient referral to medical specialists for follow-up or admission as appropriate to insure prompt and effective coverage. The center should also arrange for referral and report to a patients' personal physician, if he has one.

7. *Medical Records*

The freestanding emergency medical care center should maintain an adequate medical record for each patient and these records should be reviewed periodically by the medical director or his designee.

Arrangements for transmitting medical records to other requesting physicians should be provided.

8. *Payment for Services*

The freestanding emergency medical care center should make available emergency medical services regardless of the patients' ability to pay for such services.

To help assure adequacy of care in meeting public expectations of freestanding emergency medical care centers, the Commission on Emergency Medical Services recommends use of these initial criteria to determine whether a center can be considered able to provide "emergency" care.

The Commission further believes that public expectations of the range of services available from freestanding ambulatory centers is better met when use of the term "emergency" is confined to facilities offering a level of care consistent with these criteria.

Conclusion

The Board of Trustees commends the Commission on Emergency Medical Services for its review of the freestanding emergency medical care center question and the preparation of this report. The Board and the Commission will continue to study the appropriateness, quality and cost considerations in the provision of services by freestanding emergency medical care centers and will report as necessary to the House of Delegates.

The Board of Trustees recommends that this report be adopted in lieu of Resolutions 27 and 64 (I-81).

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Needed: A New Way to Train Doctors

(First of Two Parts)

DEREK BOK

As Harvard's medical school begins a pilot program in curricular reform, President Derek Bok appraises current discontent with medical education and the way physicians practice their craft.

Last May, at its final meeting of the year, the Faculty of Medicine gave its approval to the dean and a group of professors to create an experimental curriculum. Though limited to 25 students per year, this initiative may well turn out to be Harvard's most impressive innovation of the 1980s. Instead of merely tinkering with course requirements or shifting hours of instruction from one subject to another, the authors of the program have begun by making a fresh appraisal of the knowledge, skills, and attitudes that physicians today and tomorrow need to possess. On this foundation will be built an entirely new curriculum. Not only will it seek to alter what students learn; it plans sweeping innovations in the methods by which they are taught.

Stirrings of change are evident elsewhere in the United States. In 1982, the Macy Foundation sponsored a major conference that urged far-reaching reforms in the teaching of medical students.[1] The Institute of Medicine has just come forth with a study on medical education and societal needs.[2] For the past two years, a blue-ribbon committee appointed by the Association of American Medical Colleges has been studying medical education and will soon issue a report.

This high-level attention has not come about by chance. Many forces have combined to alter the body of medical knowledge, the way in which doctors practice their craft, and the system of delivering health care services in the country. It is only natural, then, that educators are starting to wonder how they should respond. As yet, the outcome is hard to predict. Like ancient China, medical education has experienced many assaults from the outside world without undergoing substantial change. Even so, I believe that pressures have now reached such a point that basic reforms are likely to occur. In the pages that follow, I shall consider the forces that have created this opportunity, the changes in education that seem most plausible, and the steps that Harvard Medical School plans to take to create its new curriculum.

The Revolution in Medicine

We have grown so used to a world of miracle drugs, open-heart surgery, kidney transplants, and CAT scanning that we can scarcely remember the primitive state of medical science only a few generations ago. Not until this century could patients expect to improve their chances of survival by entering a hospital.[3] Looking back to his boyhood in the 1920s, Lewis Thomas recalls how frustrated his father felt over his constant inability to comprehend, let alone cure, the ailments of his patients.[4] Even in the late Thirties, after entering Harvard Medical School, Thomas recalls that "it gradually dawned on us that we didn't know much that was really useful, that we could do nothing to change the course of the great majority of the diseases we were so busy analyzing, that medicine, for all its facade as a learned profession, was in real life a profoundly ignorant occupation."[5]

Since World War II, the pace of medical discovery has quickened, spurred by billions of dollars in federal aid each year to finance research. The knowledge of physicians has grown enormously; the methods for diagnosing and treating illness have multiplied. With government support, medical school faculties grew fivefold from 1960 to 1980, teaching hospitals transformed themselves into vast temples of research, and laboratories blossomed with equipment of immense sophistication.

As research surged forward, great changes also occurred in the system for delivering and financing health

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DEREK BOK is President of Harvard University. Copyright© 1984, *Harvard Magazine*. Reprinted by permission.

care. In particular, the federal government came to play a major role in making medical services available to all segments of society. With Medicare and Medicaid, the poor and the elderly were assured access to health care at a total cost to the taxpayer that has come to exceed $80 billion per year. These initiatives expanded the use of medical services by the aged and indigent to such a point that poor people began visiting doctors at rates exceeding those of more affluent individuals. Anticipating this growth in demand, Congress increased the supply of health services by subsidizing hospital construction and medical education. The supply of hospital beds rose by almost 50 percent while the number of medical students virtually doubled. As a result of these measures, 90 percent of the population could count on a reasonable level of medical services by 1980.

Despite these successes, the work of Congress remains unfinished. Still unrealized is a comprehensive system of care comparable to those achieved in other industrialized nations. To our shame, 28 million people are not yet covered either by federal programs or by private health insurance. With recent cuts in the eligibility and benefits under federal programs and with financial woes causing retrenchment in many municipal hospitals, patients of modest means are finding it harder to get adequate medical services when they need them.

The expansion of health services has also brought new problems in its wake. By the mid 1970s, experts began to warn that the stimulus of government programs had worked too well. Julius Richmond, former assistant secretary for health and Surgeon General, claimed that hospitals now had 150,000 more short-term beds than the nation actually needed.[6] According to the Graduate Medical Education National Advisory Committee, medical schools had expanded to the point that the nation could expect a surplus of 25,000 to 50,000 doctors by 1990.[7] The Institute of Medicine opined that far too many of our doctors were specialists and far too few were general practitioners.[8]

Changes have occurred in the content of courses. But the *methods* and the *structure* of medical education have stayed surprisingly constant through the postwar period.

Worse yet, the methods used by the government and private insurers to pay the cost of care for the aged and indigent carried no incentive to restrain expenditures. As a result, aided by the rapid growth in the number of hospital beds and practicing physicians, medical bills shot up much faster than the cost of living. Whereas the total cost of health care had consumed only 5.3 percent of the Gross National Product in 1960, the proportion rose above 10 percent by 1983, amounting to more than $350 billion per year. No other industrial nation devoted a larger share of its resources to this purpose, and most spent considerably less.

These burgeoning costs in turn have had repercussions throughout the health care system. A host of government rules have sprung up to fix the maximum price the government will pay for medical services and restrict the right to construct new hospital facilities. To foster competition, federal officials have encouraged health maintenance organizations, which offer prepaid care at prices below Blue Cross and other established insurers. Chains of hospitals operated for profit have also expanded rapidly to take advantage of growing health care markets. More recently, coalitions of corporations, unions, and doctors have formed to search for ways of curbing the rise of health care bills. These developments promise not only to transform the health system but to affect the nature and quality of care itself. For though the initiatives are very different, they do have one thing in common. All of them carry potent new incentives to press down medical expenditures. The great unknown is whether these incentives can succeed in restraining costs without causing providers to dilute the quality of care.

The Response of Medical Education

With such extraordinary advances in scientific knowledge, not to mention the metamorphosis of the health care system and its attendant policy problems, one would have expected comparable changes in the shape and substance of medical education. In fact, such changes have occurred in the *content* of courses. Instructors have been quick to tuck the latest scientific findings into their classroom lectures and their discussions on hospital wards. But the *methods* and the *structure* of medical education have stayed surprisingly constant through the postwar period. In order to enter medical school, college students must still take work in mathematics, physics, biology, and chemistry. Once admitted, they continue to spend much of the first two years listening to lectures on basic science—biochemistry, anatomy, microbiology, pathology, neurobiology, physiology, and pharmacology. During the last two years, they still enter the hospital for clinical rotations under the tutelage of professors and house staff, who teach them the arts and skills of taking medical histories, finding further information through various tests and procedures, and eventually making diagnoses and prescribing appropriate treatments.*

If the structure and methods of medical education have stayed more or less the same, so also have the critcisms and complaints. Educators have long observed that premedical requirements and prevailing admissions practices push college students into majoring in science and stir anxieties that distort the course selection and even the extracurricular activities of many undergraduates. For years, these comments were largely anecdotal. But recent research confirms the diagnosis. A survey of undergraduates in leading liberal arts colleges revealed that premeds feel greater stress than students interested in other occupations and are more likely to alter course selections and extracurricular activities to favor their chances of admission to medical school.[9] Fifty-three percent of the premeds in this survey felt that a substantial minority of their fellow students disliked them, while 24 percent believed that instructors expressed negative feelings toward them. Forty-five percent of all undergraduates who dropped their plans to become a doctor did so because they did not wish to enter a profession with a group of students who seemed so grimly purposeful and ambitious. Still worse are the persistent reports of cutthroat competition, buttressed by a study of 400 medical students in which 88 percent admitted having cheated at least once during college.[10] (This study is especially ominous since it found a positive correlation between cheating in college and dishonesty in the process of patient care.)

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*Greater changes have occurred in the residencies that make up graduate medical education, but that is a subject beyond this report, which is entirely concerned with the general preparation given to all physicians that culminates in the M.D. degree.

It is hard to overcome such pressures completely as long as there are many more aspiring doctors than places in our medical schools. Even so, except for experiments by a few schools, most of them financed by the Macy Foundation, one is struck by how little medical faculties have done to improve matters by reviewing their admissions practices and premedical requirements.

The problems of the first two years of medical school have also changed but little over the past few decades. Much of the instruction still consists of lectures in which a procession of teachers relate large quantities of scientific material to a passive student audience. The sheer weight of this material has jumped dramatically with the cascade of discoveries that followed the work of Crick and Watson on the structure of DNA. Thus far, however, faculties have typically reacted by packing their lectures more densely and cutting back on laboratory classes and independent study to make room for still more lectures.

In response to student complaints, faculties have tended to increase the number of electives or provide a bit more contact with "live" patients—palliatives that do not really attack the underlying problems. Increases in faculty size, far from encouraging more tutorial and small group instruction, have led professors to specialize more narrowly and expect lighter teaching loads. Thus, courses today are commonly divided among many lecturers in a long disjointed "parade of stars" in which the professors, one by one, appear before the students to describe new developments in their specialty. Since more and more of these instructors have received their degrees in basic science rather than medicine, their classes often seem to have little relation to the patient care that attracted most of their students to medical school in the first place. Worst of all, the lecture system encourages a static, passive attitude toward education that emphasizes memorization instead of the active, inquiring cast of mind required to keep up in a rapidly changing field.[11]

After the first two years, medical education turns highly practical. Students begin their clinical rotations in the hospital, learning the rudiments of surgery, medicine, pediatrics, and other fields of practice. At this stage, the instruction is much more relevant to the students' professional lives. The tedium and abstraction of the first two years give way to the total absorption of working with live patients. But new complaints come to the fore. Despite the huge increase since World War II in the size of the clinical faculty, students feel that they get too little instruction from professors and too much from hospital residents and interns only slightly older than themselves. They often find the content of rotations unpredictable, the objectives vague, the feedback far from adequate.

More experienced critics expand on these complaints. In commenting on the quality of teaching in the wards, they claim that students are forced to play too passive a role with insufficient opportunity to practice the skills of seeking out information, making tentative diagnoses, testing their hypotheses with further information, and eventually reaching a final conclusion. They likewise complain that students have too little exposure to the psychosocial aspects of patient care and too little discussion of preventive measures or the problems of conserving costs in gathering information and prescribing treatment.

A final criticism that applies throughout the curriculum is the lack of attention paid to the nonscientific side of medicine. Only a minority of medical faculties require their students to take a course in medical ethics, the history of medicine, behavioral science, or the organization and economics of health care. Granted, such subjects have now been introduced as electives in almost all schools. But these offerings rarely have much status in the curriculum or gain reinforcement by being integrated systematically into the clinical rotations. A look at the Harvard Medical School illustrates the problem. At present, Harvard students must take six of their 134 required credits from courses listed under Behavioral Sciences, Social Science, or Preventive Medicine—categories that include such offerings as Medical Ethics; Social History of Medicine; Literature and Medicine; Organization of Health Care; Forensic Pathology; Psychiatry and the Law; Culture and Illness; Religion and Medicine; and Science, Sex and Gender. Such requirements carry a message that all these courses together are of slight importance in the total curriculum, that each is equally relevant to the practice of medicine and that none is important enough to be required of every doctor. With this equivocal endorsement, in an environment dominated by science and research, small wonder that only three or four students in each class of

165 actually choose to take more than the bare minimum of these subjects.

Obstacles to Change

These criticisms of medical education have been repeated many times. Most of them have been heard for over seventy years. A group of Harvard professors *in 1847* made all the familiar arguments against the overuse of lectures when they opposed a move by the American Medical Association to lengthen the curriculum. Abraham Flexner, the father of modern medical education, restated these points and also called insistently for efforts to balance medical science with greater concern for the psychological and social aspects of health. Professors early in this century even questioned the effects of premedical requirements on undergraduate education when the prerequisites were first imposed.

This record provokes an important question. Why has medical education changed so little in the face of such persistent criticism, especially during an era when the field of medicine has changed so much? One important reason is that teaching stands low on the totem pole of medical school incentives. Academic advancement, professional recognition, and public acclaim all go to those who succeed in research. If the rewards of prestige favor science, the material incentives favor patient care. Teaching hospitals need academic physicians who can attract patients and fill beds, and rapidly growing faculty practice plans offer lots of money to clinicians who can do just that. Many earn over $150,000 a year, and incomes of $300,000 to $400,000 are not unknown for part-time clinical professors.

Lured by such attractive incentives, few faculty members have a strong interest in teaching and most spend little time at it. Moreover, among the various types of students that pass through medical schools and teaching hospitals, ordinary medical students rank well below the top in competing for whatever time and attention professors are willing to give. The scientists who make up the preclinical faculty are chiefly concerned with their Ph.D. students and postdoctoral fellows, who are wholly dedicated to research. To the clinical faculty, residents and fellows often seem more interesting than medical students, since they are more advanced and committed to the very specialties their professors practice.

In this environment, it is not surprising that medical education resists change, especially in the most prestigious, research-oriented schools. Basic reforms require a lot of work—to change pedagogic styles, to develop new instructional materials, to endure the frustrating trials and errors of developing novel ways of teaching. Since none of the typical incentives and rewards of academic medicine reinforces such activities, few professors will devote the time required. In addition, medical schools command less influence among their faculty members than other academic units in the university. Professors owe obligations to their hospital, where they work and receive their salaries; to their departments, which depend far more on patient fees and federal research funds than on the medical school; and even to their professional societies, which confer prestige on their members and often declare their own views on medical education. Amid these competing loyalties, most medical deans have little leverage to engineer major educational reforms.

There is yet another, subtler force at work to inhibit change. In all professions, formal education is shaped to fit the prevailing sense of how practitioners go about resolving the characteristic problems of their calling. The Harvard Business School faculty molds its curriculum and teaching to instill what F.J. Roethlisberger has described as "the administrative point of view."[12] Law professors, especially in the critical first year, teach their classes to help students learn to "think like a lawyer"—i.e., to identify legal issues in human situations, to marshal all of the evidence and arguments on every side of each issue, and then to determine which solution best fits the legal precedents and policy considerations that bear on the problem at hand. So long as the prevailing conception stays unchanged, faculties are unlikely to alter the curriculum very much.

Medicine has its own idea of what it means to "think like a doctor," even though physicians may be less explicit about it than their colleagues in business and law. At the heart of this conception is a view of human disease as a scientific phenomenon consisting of deviations from a biomedical norm. Such deviations are thought to result from a determinate cause or set of causes that are somatic or biochemical in nature. It is the physician's job to ascertain these causes by powers of observation supplemented increasingly by diagnostic tests and other technological aids, and then to cure the ailment or at least alleviate its effects through surgery, medication, or some other course of action. Doctors cannot always diagnose a disease, since their knowledge is limited. Within the realm of what is known, however, they aspire to reach a scientifically certain diagnosis by making all the relevant observations and tests, while looking to research to narrow their ignorance through the discovery of scientific truths.

Professor Donald Selden aptly summarized the traditional view in his 1981 presidential address to the Association of American Physicians:

> Medicine is a very narrow discipline. Its goals may be defined as the relief of pain, the prevention of disability, and the postponement of death by the application of the theoretical knowledge incorporated in medical science to individual patients.[13]

This conception of the doctor's role has had a marked effect on the nature of medical education. In a profession that emphasizes scientifically determined findings, rather than the rough judgments characteristic of lawyers and business executives, professors are inclined to impart knowledge didactically, as truths to be described rather than problems to be discussed. Matters outside the domain of science command little attention. Although everyone knows that psychological and behavioral factors can influence health, doctors have tended to regard these matters as unscientific and have left them largely to others—psychologists, social workers, public health officials, and the like. It is only natural, then, for medical schools to push such subjects to the margins of the curriculum. Similarly, since ethical issues and patient values have little effect on the scientific determination of disease, they have not loomed large in the thinking of physicians or faculty committees, at least until recently, when the law courts and the media began to make such problems too prominent to ignore. Much the same has been true of other subjects relevant to health, such as the prevention of disease, the cost and equitable distribution of medical services, and the development of health policies and regulations. Because these topics are peripheral to the scientific analysis of illness, they have either been relegated to secondary status in the curriculum or left to other faculties such as public administration and public health.

New Forces in the Medical Environment

Despite its restricted focus, the traditional conception of the doctor's craft rests on firm foundations. Science has vastly expanded our knowledge of the causes and cure of disease. The progress has been so impressive and its results so abundant that no account of modern medicine could fail to place the application of scientific knowledge at the very center of the enterprise. This empirical support is buttressed by compelling psychological forces. Because medical decisions have such vital effects on human lives and the consequences of error can be so severe, both doctors and patients have strong motives for believing in the accuracy and scientific authority of the physician's judgment. With these achievements and attractions, the traditional concept has much to recommend it. And yet, new forces have developed that promise not to downgrade science but to expand the physician's role to encompass added problems and complexities.

The growth of scientific knowledge itself is pressing hard against the familiar notion of what it means to think like a doctor. The constant flow of new discoveries makes impossible demands on human memory. In a world with more than 10,000 scientific journals, the traditional library can no longer succeed in giving practitioners quick, efficient access to knowledge. Already, almost 40 percent of physicians in one survey said that they could no longer keep up with developments in their field.[14] Thus, doctors increasingly need to know how to use the computer to aid them in retrieving useful information.

Rising quantities of knowledge not only place heavier demands on human memory but create new difficulties in analyzing problems. Scientific progress constantly expands the range of alternative diagnoses to be considered and the number of tests that can be given to test the clinician's hypotheses. Keeping these possibilities in mind, assessing the risks of harmful side effects from a growing number of tests and drugs, calculating the meaning to be derived from larger quantities of data—all are tasks that burden the most sophisticated minds. In the future, the public will undoubtedly make matters even harder by insisting that doctors search for diagnostic information and prescribe methods of treatment in ways that are not only effective for the patient but efficient for society by avoiding unnecessary tests and procedures.

In coping with these problems, most physicians are handicapped by their inability to work effectively with complex, quantitative data. Investigations consistently show that they often detect correlations where none exist, cling tenaciously to estimates based on poor information, and exaggerate the informational value derived from small samples.[15] As problems grow more complicated, such weaknesses become more costly; to avoid them, doctors will need to be proficient in the uses (and also the limitations) of statistics, computer analysis, and decision theory. Thus, it is not surprising that a recent poll of Harvard Medical School faculty and students revealed that the four skills most in need of greater emphasis were "assessing cost-benefit and risk-benefit considerations in the use of therapeutic technology"; "avoiding the collection of unnecessary information"; "seeking lower cost solutions to clinical problems"; and "using accepted principles of statistical inference from samples."[16]

Even more revolutionary are efforts to devise computer programs to diagnose illness and thus supplant physicians in the most central of their thought processes. For a few conditions, such as rheumatic heart disease, machines can already perform better than physicians. As yet, however, there is little prospect that computers will displace human judgments for a wide range of illness. What *is* likely is that machines will supplement the human mind by storing and manipulating large quantities of relevant data and by supplying an independent source of diagnoses to enable doctors to check their own judgments. Once again, therefore, physicians will continue to need their traditional skills but will have to know how to make effective use of computers as well.

New technology intrudes in yet another way by confronting doctors with a wider and more complicated array of ethical dilemmas. Now that life-sustaining techniques can prolong vital functions long after conscious feeling has disappeared, doctors ask whether there is any point, let alone moral duty, to maintain life on such austere terms. Complicated operations may save a child but at a cost so great that one can no longer avoid the problem of deciding what price to put upon a human life. Prenatal diagnosis may lead to moral problems if parents request abortions in order to avoid having children of a particular sex. There is no escape once dilemmas of this sort arise. With the rapid growth of malpractice litigation, not to mention investigatory journalism, such issues cannot be ignored any longer, even by the most scientifically inclined physician.

Another significant development is the growing awareness of the importance of psychological and behavioral factors in medical practice. Some statistics help to illustrate the point. Between a third and a half of all patients who visit primary care physicians have no physical (or biomedical) ailment at all. Yet studies show that physicians are much more likely to overlook significant emotional and cognitive disorders than physical ailments and symptoms.[17] Shame, guilt, and other psychological factors also affect what patients say to their doctors. In fact, studies of patient interviews indicate that up to one-half of all prior hospitalizations and other significant medical incidents are not communicated at all.[18] Doctors who fail to detect these psychological and social considerations can easily misperceive the nature of the case before them and resort to unnecessary surgery, overuse of drugs, and needless diagnostic tests—with no relief for their patients. Through lack of empathy and concern, they can drive ill and disabled people to experiment with fads, "miracle" cures, and other treatments of dubious value.

Psychological and social factors may also affect the incidence of disease itself. For example, recent studies suggest that acute grief can suppress the immune system and thus render a person more susceptible to illness; conversely, conjugal love and support appear to lower the risk of angina.[19] Doctors themselves can influence the course of sickness and cure by their behavior toward patients. Thus, a series of studies has revealed how efforts to prepare patients to cope with impending surgery can shorten the period of hospitalization and recovery.[20]

Doctors will need to be proficient in the uses (and also the limitations) of statistics, computer analysis, and decision theory.

Investigations have also shown that more than 30 percent of all patients fail to take the medicines or follow the treatments their doctors prescribe. Studies have revealed that over half of such persons do not even understand what they were told to do and that their doctors are usually at fault.[21] Presumably, even more people might follow their prescribed treatment if doctors were more adept at persuading them to do so. By virtue of their expertise and their involvement with people at particularly vulnerable times in their lives, doctors are strategically placed to persuade their patients to follow treatments and change their habits in life-enhancing ways. As psychologists have revealed, however, physicians can exert such influence effectively only if they will take the time and develop the skill to engage their patients actively in an effort to understand the need to alter their behavior.[22] In other words, effective practice again requires an understanding of psychology as well as biomedical science.

The final force pressing in upon the doctor is the nationwide concern over rising health costs. Over the next generation, this problem is bound to grow. On the one hand, expenses will continue to be pushed upward by increases in the aged population and in the number of doctors. On the other, government, corporate employers, unions, and large insurance carriers have become concerned enough over spiraling medical bills to resist with determination. A major battle is clearly in the making. Government regulations will probably become more intrusive. Health maintenance organizations, government agencies, coalitions of employers, unions, and carriers, even for-profit hospital chains, will press increasingly for lower costs. To achieve their ends, these organizations will try to limit the doctor's authority over patient care by imposing checks on decisions to hospitalize patients, set the length of hospital stay, or order the use of expensive procedures and tests. In order to avoid unwarranted restrictions, let alone contribute to the national effort to contain rising costs, physicians will have to know more about the issues of health care policy and administration.

Transcending these developments and drawing from them all is a growing change in the perception of how physicians go about making their characteristic decisions of diagnosis and treatment.[23] Fewer doctors are now inclined to think of themselves as simply arriving at logically determined conclusions by applying scientifically tested truths to experimentally derived data. The world today seems much more complicated. Doctors are constantly forced to make educated guesses based on imperfect information. Diseases often have multiple causes, not all of them scientific in nature. The information physicians receive, the symptoms they observe, the outcome of the treatments they prescribe, can all be affected by the ways in which they act and interact with patients. The decisions they make are limited not only by gaps in biological knowledge but by bureaucratic rules and economic pressures. In short, the doctor's world cannot be restricted to science or neatly divided between the known and the unknown. Considerations of many kinds are often jumbled together to form a picture full of uncertainties, requiring the most delicate kinds of judgments and intuitions.

This conception of the doctor's craft may not be entirely new, but it is surely understood more widely and more vividly than ever before. In its wake come many questions. How does one make wise judgments or probabilistic estimates from various kinds of imperfect data? If doctors do not simply act on scientific truths but often take calculated risks, how much should they tell their patients and how big a role should the latter play in deciding what chances to take with their own health and well-being? Since looking for evidence costs money—over $20 billion are spent each year on diagnostic tests alone—how much information should clinicians seek and how can they search for data in a more cost-effective manner? Finally, if the doctor's behavior helps determine what patients reveal about their ailments, how quickly they recover from an operation, or whether they follow a prescribed treatment, how can physicians conduct themselves to exert the most constructive influence?

Confronted by such problems, doctors could easily react by clinging resolutely to their traditional role as applied scientists seeking accurate biomedical explanations for a patient's disease. After all, it is hard enough to cope with the mounting complexity of the biosciences without having to take account of computers, decision trees, health care regulations, ethical constraints, and the vagaries of patient psychology. But is there a viable alternative?

Conceivably, doctors could try to avoid these complications by delegating responsibility to others. Hire philosophers, as a few hospitals have done, to deal with difficult ethical dilemmas. Leave the psychological problems of patient care to psychiatrists, social workers, and members of the clergy. Find more skillful administrators in the hospitals to cope with government regulations, and trust the AMA to make sure that public officials do not press too far on the doctor's prerogatives. Refer the statistical manipulations and data analysis to computer experts who will advise physicians on request.

Tempting though this response may seem, it is bound to fail in the end. The point is not that social workers, administrators, lobbyists, ethicists, and computer analysts are incapable of helping. Indeed, they must help. But the critical decisions cannot be cut into separate parts and entrusted permanently to specialists. Eventually, a physician must take the pieces and fit them together to form a coherent plan of action. Only doctors can decide what to do with alternative computer diagnoses after giving due weight to their own observations and impressions. Rarely will a doctor be able to delegate the final decision whether the knowledge to be gained by another test is worth the cost. Physicians will normally know more than anyone else about their patients' condition and thus will be best able to prepare them to make intelligent judgments about alternative treatments. Similarly, physicians will often command greater respect than priests or social workers in convincing patients of the steps they need to follow to cure their present disease or avoid future illness.

In sum, there is no substitute for doctors who can understand and integrate a range of subjects quite outside the body of bioscientific knowledge. Those who acquire this proficiency will serve their patients, and the public, better. But it is no longer a question of whether physicians *choose* to respond. The world outside will force them in this direction. Hospital chains and health maintenance organizations are bound to employ an increasing share of the nation's doctors. In a more competitive environment, these organizations will want to hire practitioners trained to gather information economically, to make cost-effective decisions, to motivate patients to comply more willingly with health-preserving regimens. The rising flood of relevant information will compel doctors to use new technological aids. Law courts and newspapers will push ethical issues to the fore, and those who ignore them will be penalized. In today's environment, then, small wonder that medical schools are beginning to think about basic educational reform. The blunt fact is that most of their students today are getting an education that is far too narrow to prepare them for the challenges that await them in their working lives.

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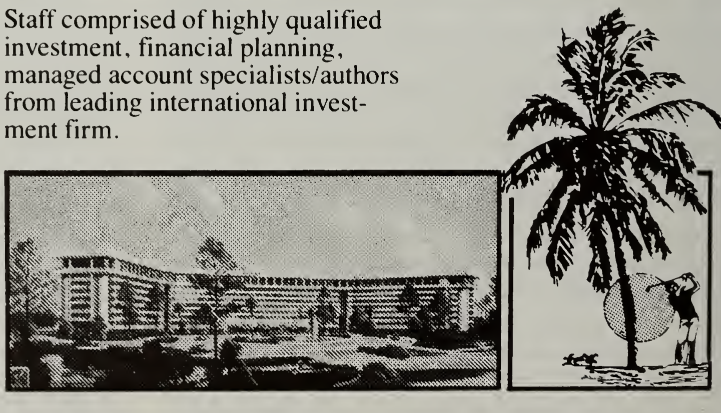

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Month in Washington

HCFA Adds New Wrinkle To Fee Freeze . . . AMA Intends To Sue

Medicare officials charged with designing a new system to freeze and monitor physician fees added a new wrinkle to a system in early August. And on August 28, the AMA Board of Trustees announced the Association's intention to file a law suit challenging the constitutionality of the provisions of the Medicare amendments passed with the Deficit Reduction Act of 1984.

The HCFA modifications responded to concerns of beneficiary representatives, particularly the 16 million member American Association of Retired Persons. As first contemplated, the monitoring system would have compared physician's charges during the 15-month freeze with his or her highest charge for the same procedure during the three month base period from April-June 1984. As described to American Medical Association representatives on August 10, however, it now would compare both the highest charge and the "customary charge pattern."

The modification would affect "nonparticipating physicians" who have maintained more than one fee structure for some services. It means they will be monitored by the carriers and the government to determine whether the distribution of charges among patients has become more heavily weighted toward the higher charges. Extreme shifts in the intensity of procedures billed for Medicare patients would also be flagged.

If, during the base period for example, a physician had charged 80% of his Medicare patients $25 for a regular office visit and charged the other 20% of Medicare patients (such as those eligible for Medicaid) $15, he would be flagged when the distribution of charges shifted to 90% at $25 a visit and 10% at $15 a visit.

Medicare carriers are expected to identify and monitor for each nonparticipating physician his or her 10 most frequent services and another 10 procedures chosen at random.

Surgeons will probably be monitored for more than 20 procedures.

If the monitoring system flags increased charges or variations in the distribution of charges, the Medicare carrier will contact the physician for an explanation. If the physician cannot provide a sufficient explanation, he or she will be monitored monthly. If the pattern continues, the case would be referred to the HHS Inspector General for possible sanctions including fines or "debarment" from Medicare.

HCFA officials previously had intended to send two letters to physicians; the first explaining the mandates of the law that created the freeze; the second to include a participation agreement for physicians who agree to accept 100% of Medicare cases on assignment.

The explanation and the participation agreement have now been combined in single letter which was sent to physicians late in August. Participation agreements must be signed and mailed to the carrier by October 1.

On or about October 1, the Medicare carriers – upon request – will provide physicians with a preliminary profile of their charges during the base period. Final profiles will not be available until January, since some claims may not be filed until the end of the calendar year.

* * * *

AMA Will Sue Over Medicare Amendments

The American Medical Association Board of Trustees on August 28 announced the Association's intention to file suit challenging the constitutionality of the Medicare amendments passed with the Deficit Reduction Act of 1984 containing the reimbursement freeze under Medicare and provisions establishing "participating" and "nonparticipating" classes of physicians.

Announced by AMA Board Chairman John J. Coury, Jr., M.D., the statement said that the AMA believes that the amendments will deny Medicare beneficiaries the ability to select the physician from whom they will receive care. In addition, the legislation freezes non-participating physicians' fees to Medicare patients until October 1, 1985. This singles out non-participating physicians, alone among all segments of our society, by forbidding them from freely entering into contractual agreements with patients.

Prepared by the Washington, D.C.
Office of the American Medical Association

The Act authorizes penalties against non-participating physicians (those physicians who do not agree to accept assignment in 100% of their Medicare cases) who raise their charges.

Finally, the provisions that mandate restrictive fee schedules for clinical laboratories will deprive Medicare beneficiaries and others of complete medical services by promoting the reduction of those services, particularly in small and rural communities.

The AMA is concerned that this legislation will seriously jeopardize the availability, access and complete delivery of medical services to the American people.

* * * *

Cyclamates Revisited

Reconsidering its 14-year ban, the Food and Drug Administration has asked scientists to take a second look at the 21 studies of the artificial sweetener.

Cyclamate dominated the artificial sweetener market in the 1950s and 1960s, with sales totalling a billion dollars a year and consumption running as high as 18 million pounds a year. As a table-top, low calorie sweetener, it was marketed under the trade name "Sucaryl" and promoted for obese persons and diabetics.

When a single rat study in Canada indicated that the sweetener caused bladder tumors, however, the FDA banned its use in 1970. This rat study later was criticized by the American Statistical Association and American Society of Toxicologists, which cited statistical fallacies and biased methodology.

Now, the FDA has reevaluated the research, finding "very little credible data" that cyclamate causes cancer in animals. FDA's new report, based on an internal study completed last April, especially criticizes the Canadian rat study.

"Cyclamate . . . is not carcinogenic," asserts the new FDA report. Moreover, it adds, "no newly discovered toxic effects of cyclamate are likely to be revealed if additional standardized studies were performed."

FDA scientists have concluded that the results of the controversial rat study "are confounded, not repeatable, and not explicable." The strain of rats in which tumors were found is now believed to spontaneously produce tumors, which may be unrelated to cyclamate consumption.

Just to be sure, the FDA has asked the National Research Council to conduct an independent assessment of the product under a $390,000 contract. The NRC review will be complete next March.

* * * *

Smith-Kline Charged On Heart Drug

For the first time in history, the U.S. Justice Department in August filed criminal charges against a pharmaceutical company for failing to promptly report to federal officials the toxic side effects of a drug.

The drug, Selacryn (ticrynafen), has been linked to tentatively 25 deaths and 340 cases of liver and kidney disease.

The Smith-Kline Corporation and four company officials waited 36-105 days before reporting cases of liver damage in patients taking the anti-hypertensive drug, the government says. Federal law requires that drug companies report unexpected adverse effects to the Food and Drug Administration within 15 days of receipt of information.

Fourteen counts charge that the company and three of its physicians failed to report these adverse effects. Twenty additional counts against those parties and a fourth physician charge that the drug label contained inaccurate information, claiming that no causal relationship had been established between the drug and subsequent liver damage.

All charges are misdemeanors because there is no evidence of willful violation of the law. Among those charged are officers of United States Pharmaceutical Products, an S-K subsidiary.

* * * *

HCFA Officials Deny Rationing Under PROs

Federal officials in charge of Medicare's new peer review organization system have sought to diffuse charges that the system relies on state quotas that could lead to rationing of care for elderly and disabled beneficiaries.

Health Care Financing Administration officials defended their implementation of the PROs at a Senate Finance Health Subcommittee hearing. Subcommittee Chairman David Durenberger (R-MN), who sponsored the original PRO legislation, held the hearing in response to widespread criticisms stemming from the first PRO contracts.

The criticisms centered on admissions and quality objectives in the contracts that specified percentages and numbers of cases by which the PROs intended to reduce certain types of admissions, hospital complications and "avoidable deaths."

The major questions centered on how the goals were arrived at, whether they are achievable, and how strictly HCFA will hold the PROs to the objectives in their contracts.

Several of the witnesses—including representatives of the American Medical Association and the American Medical Peer Review Association urged that the PRO contracts be modified to specify that contracts could be renegotiated. Sen. Durenberger questioned HCFA's decision to seek actual reductions in admissions rather than simply trying to hold the line under the new diagnosis related group (DRG) payment system which critics say could increase hospital admissions.

HCFA Administrator Carolyne Davis insisted that the objectives should be viewed as targets not quotas. She told Durenberger that his legislation's requirement of performance-based contracts necessitated the development of specific numerical "milestones" against which to measure the PRO performance.

Davis also contended that although the PRO bidders worked within HCFA parameters, the bidders set their own goals, surprising the HCFA officials in some instances with the "ambitiousness" of the proposals. She claimed the objectives "are achievable" and defended the decision to call on PROs to reduce rather than simply hold down admissions.

The HCFA Administrator pledged, however, that "even though we are being specific in contracts, we do not intend to be rigid or inflexible if we learn, during the course of the contract, the numbers should be modified. We are always ready to renegotiate with the PROs if they have overstated the nature of a particular problem, or if they have identified a more pressing problem for review, or even if the statistics they used to develop the objective in question were incorrect."

Davis, who also pledged to work with hospital and medical groups in implementing the program, met with the AMA, AMPRA and the American Hospital Association August 21.

* * * *

Physicians To Be Recruited For Research

The National Institutes of Health and the Howard Hughes Medical Institute in August launched a new multi-million dollar program to boost biomedical research and increase the flow of new physicians into research careers.

The program will chose 30 medical students a year for six months to a year of research under the guidance of NIH scientists. Recruitment will begin this fall, with the first group of students entering the program in the fall of 1985.

"It is expected that this early exposure to the excitement and intellectual challenge of research—after the second year of medical school—will encourage more medical students to undertake careers in biomedical research," said Donald S. Fredrickson, M.D., president of the Hughes Medical Institute (HHMI).

There is a serious shortage of physicians in research, say authorities. The consequence, they fear, may be a breakdown in the transfer of knowledge from the lab to the bedside.

HHMI, one of the largest private medical research organizations in the world, will support the program at a cost of $10.5 million for the first five years, which includes stipends, travel and support for the students, and building renovation and construction. NIH and HHMI will cooperate on selection of students, couseling, teaching, and interaction with students when they return to their home institutions.

* * * *

Tougher Labels For Two Anti-Inflammatories

Facing growing criticism of the safety of two anti-inflammatory drugs, the Department of Health and Human Services (HHS) has decided this month to keep the drugs on the market, but toughen up their labeling.

The drugs are overprescribed, not uniquely beneficial for any illness, and are too often administered for acute conditions such as tennis elbow or bursitis, HHS Secretary Margaret Heckler announced. She fell short of recommending withdrawal, however. The evidence does not indicate that the drugs pose an imminent hazard to public health, or that their approval applications should be suspended, she said.

The drugs—phenylbutazone and oxyphenbutazone, marketed since 1952 and 1961 under the trade names Butazolidin and Tandearil, respectively—face declining popularity, as safer alternatives have become available.

The public interest organization Health Research Group recently petitioned HHS to pull the drugs off the market, saying they have caused more than 10,000 deaths among the 135 million people who use them worldwide. Several other countries—including Britain, Sweden, Norway and Israel—have removed the drugs from the market or restricted their use.

Secretary Heckler rejected the HRG petition, but proposed the following changes:

- the medicines should be available for chronic arthritis victims in whom the risk of fatal blood disorders is reasonably related to the benefits.
- the labeling should be tightened to emphasize to doctors that they should not prescribe the drugs for acute, self-limiting conditions.

* * * *

Custis To Serve Paralyzed Vets

Donald L. Custis, M.D., former medical director of the Veterans Administration, announced this month that he will serve as director of medical services for the Paralyzed Veterans of America (PVA).

In his new position, Dr. Custis will coordinate PVA's programs that care for veterans with spinal cord injuries. PVA, a long-time supporter of spinal cord research, is hoping to boost the number of young physicians in the field of injured veteran care.

HCFA Lowers DRG Payments To Hospitals

New data indicate Medicare hospital payments for fiscal 1985 should be even lower than the limits proposed in July, Health Care Financing Administration officials told a Senate panel in August.

The proposed increase of about 4% is regarded as inadequate and unfair by hospitals and some Congressmen, however, and HCFA Administrator Carolyne Davis, Ph.D., said the industry and Congressional objections will be weighed against the implications of the new data in determining whether to adjust the proposed payment levels. She warned, however, that if the current payment formula is challenged, similar results can be achieved through other less equitable adjustments.

The levels proposed in July would result from a 5.6% increase in DRG rates combined with a 2.4% across-the-board decrease in DRG weights.

Davis told the Senate Finance Health Subcommittee on August 8 that the adjustment was necessary to comply with the "budget neutral" requirements of the DRG law. She maintained that the 2.4% adjustments in weights was required because hospitals had upgraded the intensity of their coded admissions by more than anticipated.

Hospitals contend that the changes in coding reflect actual changes in their patient case mix and claim that HCFA is misconstruing the "budget neutrality" provisions. Both Finance Committee Chairman Sen. Robert Dole (R-KS) and Subcommittee Chairman David Durenberger (R-MN) have asked the Reagan Administration to reconsider its proposed payment levels. According to news reports, HHS Secretary Margaret Heckler intends to honor their requests and direct that the weight reduction not be included in final regulations due September 1.

* * * *

Dr. Young Becomes New FDA Commissioner

Frank E. Young, M.D., was sworn in in August as new Commissioner of the Food and Drug Administration, ending an 11-month hiatus since Arthur H. Hayes, M.D., left the post last fall.

Young, a microbiologist who has been dean of the University of Rochester medical school since 1979, will oversee roughly 7,000 FDA employees at the agency's headquarters in Rockville, MD, the National Center for Toxicological Research in Jefferson, AR, the Engineering and Analytic Center in Winchester, MA, and 12 laboratories and seven specialized research centers.

"There are few tasks more demanding in federal service than heading up the FDA, an agency which oversees the safety and efficacy of what we eat and the medicines to cure our ills," said HHS Secretary Margaret Heckler. Dr. Young's responsibility, she said, "is to balance technical breakthroughs and public health."

The current "explosion" of research offers huge benefits, Dr. Young said. "I welcome the challenge to apply ever-expanding science to political decisionmaking. We at FDA must chart a course through these turbulent times," he said.

Dr. Young first went to Rochester to serve as chairman of the department of microbiology and professor of radiation biology, pathology, microbiology and biophysics. While there, he developed a laboratory for research into vaccine development and gene cloning, publishing more than 150 articles.

* * * *

Adverse Reactions To Food

The Allergy and Infectious Disease Institute at NIH has produced a report called "Adverse Reactions to Foods." The report is an attempt to come to grips with controversial questions about food allergy and its management. The problem has plagued the practicing allergist in recent years, mostly because advancing technology permits much more precise measurements of allergic response than were available when food allergists first began treating patients with food allergies. Much of this new work has raised doubts about these earlier therapies.

A few years ago the allergy institute made an attempt to resolve the issue through a consensus development conference. But proponents of some aspects of food allergy testing and management, fearing their clinical practices threatened, torpedoed the conference before it could get organized.

The present report, which was produced in association with the American Academy of Allergy and Immunology, attempts a dispassionate approach, examining the present status of research in the field with the idea that this will provide some guide to what might be a profitable research avenue to follow.

* * * *

Abnormal Cells Held Suitable For Vaccine Production

The use of abnormal cells for cultivating viruses for vaccines got something approaching a green light from participants at a two-day meeting at NIH at the end of last month. For years cells that had evidence of potential carcinogenicity such as an abnormal chromosome number were viewed with suspicion as materials on which to cultivate viruses for human vaccines.

Today, however, the conference agreed, the methods of "cleaning up" the final product—a suitable antigen—have now reached the stage where it is highly unlikely that any DNA with malignant potential is left.

The result will be to permit the use of cells such as Vero cells, for example, on which to cultivate poliovirus for the new Salk inactivated polio vaccine. Vero cells are a subhuman primate cell line. The use of these cells is crucial to the success of this vaccine since this depends on very high titers of virus which can only be economically achieved on such cells. It also opens the way to using malignant cell lines for any possible anti-AIDS vaccine since the agent most closely identified with AIDS, HTLV-III, can only be grown on a human leukemia cell line.

Legal Aspects of Peer Review

SUSAN M. SCHMIDT, J.D.

Introduction

Medical peer review is an indispensable part of modern medical practice. Peer review may be mandated or it may be voluntarily undertaken. It may be required by state licensure laws, federal laws, accreditation standards, or by individuals seeking to improve the quality of medical care in an institution. The review may be conducted within a particular institution, by an independent organization, by a medical society, or a variety of other individuals or groups. The review may focus on the appropriate utilization of services or facilities, analyze medical practices, recommend credentials decisions, or affect other aspects of patient care or medical services.

Courts have recognized the necessity of peer review activities. In *Bredice v. Doctors Hospital,* the court noted that the purpose of the meetings "... is the improvement, through self-analysis, of the efficiency of medical procedures and techniques. They are not a part of current patient care but are in the nature of retrospective review of the effectiveness of certain medical procedures. The value of these discussions and reviews in the education of doctors who participate, and the medical students who sit in, is undeniable .... There is an overwhelming public interest in having those staff meetings held on a confidential basis so that the flow of ideas and advice continue unimpeded."[1]

For the physician involved in peer review activities, various questions arise: what is the legal liability exposure, will the proceedings and reports be accessible to medical negligence plaintiffs or others, and can members of a review committee be subpoenaed or deposed? No single answer applies to all of these questions in every state. The legal issues that arise involve both the common law and state statutes.

This article will discuss the most common theories of legal liability that arise and the various protections afforded to physicians involved in peer review activities.[2] The peer review protections applicable under Connecticut law will be discussed.

Potential Legal Liability

Defamation

One of the most frequent allegations that arises from peer review activities involves defamation. Defamation is injury to a person's "reputation." One authority defines defamation as a communication that tends "to diminish the esteem, respect, goodwill, or confidence in which the plaintiff is held or to excite adverse, derogatory or unpleasant feelings against him."[3] To establish the legal cause of action for defamation, the plaintiff must establish that a written or oral communication was published to a third person by the defendant and that the third person became aware of its derogatory meaning.

Various defenses exist to a defamation allegation. Truth is an absolute defense. A conditional, or qualified, privilege exists with regard to communications made in good faith, without actual malice, when reasonable or probable grounds exist for believing the statements are true. Further, the communication must be one in which the author has an interest, or a public duty of a legal, judicial, political, moral, or social nature, and the communication must be made to a person with a corresponding duty.

The scope of this cause of action as applied to peer review activities is evident. The communications should be made in good faith and reasonable care should be taken to insure their truth. The information should be conveyed only to those persons who have an interest in receiving them, that is, persons who have the authority or responsibility to act on them. Peer review proceedings and opinions should not be repeated to persons not involved in the peer review process.

Courts have recognized the applicability of the qualified privilege doctrine to members of hospital medical staff and medical society committees responsible for evaluating the professional competence of colleagues. The courts tend to balance the obligation of the

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SUSAN M. SCHMIDT, J.D., staff attorney Health Law Division, Office of the General Counsel of the A.M.A.

medical profession to assure the public of competent practitioners and the right of the physicians to maintain their reputations in the community. The court, in *Kinney v. Daniels,*[4] applied these principles. The Chief of the Medical Service reviewed the practice of a physician who had placed several patients on dialysis. During this review, the physician requested review reports from several members of the Internal Medicine department. The letter sent to the physician that questioned the propriety of the physician's activities was also sent to three other physicians who, in some manner, were responsible for privilege review and peer review in the hospital. The court found that the publication of the letter to these three physicians was within the common law, qualified privilege to defamation actions. The court stated that given the letter's substantial truth and limited publication in the context of health care peer review, the privilege applied.

Antitrust Liability

To maintain an antitrust action, the plaintiff must satisfy a threshold requirement that the activities of the peer review committee affect interstate commerce within the meaning of the Sherman Act. In addition, the plaintiff would have to show that the physicians involved with the peer review combined or conspired to restrain trade or monopolized or attempted to monopolize within the meaning of the Sherman Act.[5] These requirements often are difficult to establish.

So long as the activities are within the legitimate scope of the peer review process and do not have an improper anticompetitive effect, antitrust liability should not exist. A recognized impermissible anti-competitive purpose is if a member of a peer review committee has an independent stake, usually economic, in achieving the object of a conspiracy.

Sokol v. University Hospital, Inc.,[6] discusses these antitrust arguments. In that case, the district court discussed whether the denial of staff privileges constituted an antitrust violation. The court said that the denial was "... an isolated instance of the restriction on one doctor's privileges, which may be analogized to a refusal to deal in commercial situations. This has not been held to violate the Sherman Act in the absence of an agreement, combination, or conspiracy. Where the act complained of is an act of the corporation, the fact that the concurrence of a number of the personnel of a corporation is required to generate the corporate act does not satisfy the Sherman Act's requirement of an agreement, combination, or conspiracy."[7] Therefore, if the peer review activities are conducted properly, a court would have difficulty in establishing that a conspiracy existed.

Breach of a Confidential Communication

The relationship between physician and patient is extremely confidential. A physician who reveals a patient's confidential communications violates ethical principles unless the patient has authorized the release or it is required by law.[8]

The likelihood of a suit being brought because of a breach of confidentiality is remote. The review can be made by using a coding system to ensure anonymity of the patient, and the review is performed by physicians who are aware of the need for confidentiality. So long as the information is used for legitimate purposes no breach of confidentiality should arise.

The issue of whether an internal hospital committee may examine patient records was raised in *Kluge v. Lutheran Medical Center of St. Louis.*[9] The court recognized the hospital committee's right to review patient records and noted that the confidentiality of the patient's name can be assured in these proceedings.

Statutory Privilege

All fifty states and the District of Columbia have enacted laws that restrict, to some degree, the civil liability of persons involved in medical peer review and the discovery and admissibility of peer review proceedings.[10] Some statutes provide complete protection of all activities and documents while others are not so comprehensive. At a minimum these statutes usually codify the conditional privilege that applies to defamation actions. The statutes vary in the scope of persons they cover. Some laws only cover physician members of the committees while others extend to agents and consultants of the committee and persons who provide information to or testify before the committee. Almost every statute provides immunity only to those persons who act without malice and in good faith. Some statutes require, in addition, that a reasonable effort must be made to ascertain the facts.

The discovery of peer review activities addresses conflicting goals of opening up the litigation process and insuring confidentiality. Without confidentiality, physicians would be more reluctant to serve on these committees and necessary professional self-evaluation would not occur. The value of self-evaluation has been recognized by courts and legislatures. Others argue that airing the truth about an incident is more valuable.

When evaluating whether certain communications are protected the wording of the statute is very important. For example, although the medical peer review proceedings are protected from discovery, the fact that they occurred may not be. Further, the statute, by its terms, may not prevent members of the medical review process from testifying if they have independent knowledge as to a particular physician's quality of practice that was not obtained through the peer review proceedings. Not all review documents may be protected. Incident reports that are not specifically mentioned in the statute probably are discoverable. Further, the laws generally cover only the medical review proceedings, not discussions about those proceedings after or outside of the meeting.

Connecticut Statute

Connecticut law defines peer review as "the procedure for evaluation by health care professionals of the quality and efficiency of services ordered or performed by other health care professionals, including practice analysis, inpatient hospital and extended care facility utilization review, medical audit, ambulatory care review and claims review."[11] The definition of a health care practitioner is very broad and includes persons and institutions providing care and their employees and agents.[12]

The Connecticut law protects any person who provides a broad scope of information to a variety of groups involved in insuring the provision of competent medical services when the information is intended to aid in the evaluation of the qualifications, fitness or character of a health care provider.[13] The communication must reasonably be believed to be true. In this situation no cause of action may arise and no monetary liability will attach.

The statutory protection extends to persons who serve on medical review committees.[14] So long as the activities are within the scope of the committee's functions and the member has taken an action or made a recommendation without malice and in the reasonable belief that the action or recommendation was warranted, no monetary liability will arise. Further no cause of action for damages will arise.

The proceedings of the medical review committee are not discoverable or admissible into evidence in any civil action for or against the health care provider arising from the subject under review.[15] No one at the meeting is permitted to testify in any such civil action as to the content of the proceedings except in enumerated statutory situations.[16] The exceptions include testimony concerning writings made and facts known independently of any proceeding. Data discussed or developed during peer review proceedings concerning the termination or restriction of staff privileges may be used in health care provider proceedings concerning the termination or restriction of staff privileges. In addition, the disclosure of the fact that staff privileges were terminated or restricted also is not privileged.

A Connecticut case, *Morse v. Gerity,* involved a medical negligence action. The plaintiff subpoenaed certain documents, including peer review information, concerning the physician defendant.[17] The issue before the federal district court was whether a connection must exist between the civil action in which discovery is sought and the subject matter under review by the committee in order to apply the statutory privilege. The Connecticut law did not state whether the privilege was meant to only apply to review committee proceedings involving the patient who was suing the physician or all peer review proceedings in which the physician had been involved. The court stated that if the legislature intended the privilege only to apply to peer review proceedings connected to a lawsuit, that statutory language could have been used. Instead, broad language was used. The court said that "if the purpose of the statute is to encourage doctors to evaluate their peers without fear of disclosure, that purpose would be hampered by public release of any proceedings, not just those involving the patient who has sued. The danger of inhibiting candid professional peer review exists by the mere potential for disclosure .... No chilling effect can be tolerated if the committees are to function effectively."[18] Complete confidentiality was of overriding importance. The court held that the Connecticut law prohibited discovery of all peer review proceedings.

Pisel v. Stamford Hospital[19] discussed the statutory provision that precluded testimony by someone who attended a review proceeding. The physician was asked a hypothetical question based on the evidence in the case. The defendant objected to the physician testifying because he had attended a claims review meeting. The court stated that the defendant construed the statute too broadly. It said "[t]he purpose of these statutes is to keep peer review studies, discussions and deliberations confidential. A facial examination of the statutes reveals that they are not designed to disqualify a doctor from testifying. Rather, they seek to circumscribe the subject matter of his testimony by precluding him from disclosing those matters that were part of the peer review proceedings."[20] The physician was not asked to testify as to what happened at the meeting so was not disqualified as a witness. Since this case has been decided, the Connecticut statute has been amended. The statute now enumerates exceptions to the privilege.[21] These exceptions still do not appear to cover this situation.

Conclusion

General agreement exists that only the medical profession is qualified to evaluate the professional competence of physicians and the quality of medical care that they provide. Public policy favors protecting those activities of the profession designed to improve standards of professional competence and evaluate the quality of care available to the public. In every state, laws codify the protection, although no uniformity exists. Courts, in reaching their decisions, recognize these public policies and legislative goals. For these reasons, conducting objective peer review of the professional competence of colleagues does not appear to increase the liability exposure of physicians. However, the limits of these protections are defined by law and the physician who participates in peer review activities is advised to be aware of the scope of the applicable state law.

REFERENCES

1. 50 FRD 249 (DDC 1970).
2. A comprehensive discussion can be found in Peer Review: A Legal Update, American Medical Association, 1981.
3. W Prosser, Handbook of Tort Law, §111 (4th Ed 1971).
4. 574 F Supp 542 (SD W Va 1983).

5. 15 USC §§1, 2.
6. 402 F Supp 1029 (D Mass 1975).
7. Id. at 1030. See Smith v Northern Michigan Hospitals, 703 F 2d 942 (6th Cir 1983) and Pontius v Children's Hospital, 552 F Supp 1352 (WD Pa 1982) (in which the courts found that no independent stake or intracorporate conspiracy existed.)
8. Opinion 5.05, Confidentiality, Current Opinions of the Judicial Council of the American Medical Association, 1984. Some states have codified the confidentiality principles. Legal and ethical exceptions to confidentiality requirements are recognized.
9. 518 SW 2d 157 (Mo 1974).
10. See Peer Review: A Legal Update, supra, note 2.
11. Conn Gen Stat §38-19(a)(ii) (Supp 1984).
12. Conn Gen Stat §38-19(a)(i) (Supp 1984). "Health care provider" means any person, corporation, facility or institution licensed by this state to provide health care or professional services, or an officer, employee or agent thereof acting in the course and scope of his employment.
13. Conn Gen Stat §38-19(a)(iii) (Supp 1984). "Professional society" includes medical, psychological, nursing, dental, natureopathic, osteopathic, optometric, pharmaceutical, chiropractic and podiatric organizations having as members at least a majority of the eligible licentiates in the area or health care facility or agency served by the particular society.

    Conn Gen Stat §38-19(a)(iv) (Supp 1984). "Medical review committee" shall include any committee of a state or local professional society or a committee of any health care institution established pursuant to written bylaws, and any utilization review committee established pursuant to Public Law 89-97, and a professional standards review organization or a statewide professional standards review council, established pursuant to Public Law 92-603, engaging in peer review, to gather and review information relating to the care and treatment of patients for the purposes of (1) evaluating and improving the quality of health care rendered; (2) reducing morbidity or mortality; or (3) establishing and enforcing guidelines designed to keep within reasonable bounds the cost of health care. It shall also mean any hospital board or committee reviewing the professional qualifications or activities of its medical staff or applicants for admission thereto.

    Conn Gen Stat §38-19(b) (Supp 1984). There shall be no monetary liability on the part of and no cause of action for damages shall arise against, any person who provides testimony, information, records, documents, reports, proceedings, minutes or conclusions to any hospital, hospital medical staff, professional society, medical or dental school, professional licensing board or medical review committee when such communication is intended to aid in the evaluation of the qualifications, fitness or character of a health care provider and does not represent as true any matter not reasonably believed to be true.
14. Conn Gen Stat §38-19(c) (Supp 1984). There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any member of a medical review committee for any act or proceeding undertaken or performed within the scope of any such committee's functions provided that such member has taken action or made recommendations without malice and in the reasonable belief that the act or recommendation was warranted.
15. Conn Gen Stat §38-19(d) (Supp 1984). The proceedings of a medical review committee conducting a peer review shall not be subject to discovery or introduction into evidence in any civil action for or against a health care provider arising out of the matters which are subject to evaluation and review by such committee, and no person who was in attendance at a meeting of such committee shall be permitted or required to testify in any such civil action as to the content of such proceedings; provided the provisions of this subsection shall not preclude (1) in any civil action, the use of any writing which was recorded independently of such proceedings; (2) in any civil action, the testimony of any person concerning the facts which formed the basis for the institution of such proceedings of which he had personal knowledge acquired independently of such proceedings; (3) in any health care provider proceedings concerning the termination or restriction of staff privileges, other than peer review, the use of data discussed or developed during peer review proceedings; or (4) in any civil action, disclosure of the fact that staff privileges were terminated or restricted, including the specific restrictions imposed, if any.
16. Id.
17. 520 F Supp 470 (D Conn 1981).
18. Id. at 472.
19. 430 A 2d 1 (Conn 1980).
20. Id. at 9.
21. See fn 15, supra.

Profit in Medicine: The Impact on Hospital Staffing Patterns and Physician Practice Behavior

AMA CENTER FOR HEALTH POLICY RESEARCH

The rapid growth of proprietary hospitals in recent years has raised concerns about the role of profit in the practice and delivery of medical care. In particular, these concerns have focused on the role that investor-owned hospitals would have on physicians' clinical decisions. In a recent SMS Report entitled "The Role of Profit in Medicine" (Vol. 2, No. 8), selected practice characteristics of physicians in proprietary and nonproprietary hospitals were compared. This investigation is continued here by examining the staffing patterns and practice conditions of physicians in proprietary and nonproprietary hospitals. In particular, this report examines the:

- medical staffing patterns of proprietary and nonproprietary hospitals; and
- development and/or implementation of programs designed to monitor and influence physician behavior in the hospital by proprietary and nonproprietary hospitals.

The data are taken from two sources. Information on staffing patterns within proprietary and nonproprietary hospitals are from the 1982 American Hospital Association Annual Survey, a national survey of all hospitals in the United States. Data on hospital programs designed to influence physician practice behavior are drawn from the First Quarter Survey of the AMA's 1984 Socioeconomic Monitoring System (SMS). This survey consists of interviews with 1,208 physicians. The overall response rate was 65.6 percent.

Medical Staffing Patterns in Proprietary and Nonproprietary Hospitals

A key issue in the debate regarding proprietary and nonproprietary hospitals is whether medical staffing patterns in proprietary hospitals are different from medical staffing patterns in nonproprietary hospitals. This section compares by specialty and hospital ownership: (1) the number of active and associate medical staff per 100 hospital beds, and (2) board-certified active and associate medical staff per 100 hospital beds.

Table 1 indicates that, on average, proprietary hospitals have more medical staff and board-certified medical staff per 100 beds than do nonproprietary

Table 1
MEDICAL STAFFING PATTERNS IN PROPRIETARY AND NONPROPRIETARY HOSPITALS*
(per 100 hospital beds)

	Medical Staff		*Board-Certified Medical Staff*	
	Proprietary	*Non Proprietary*	*Proprietary*	*Non Proprietary*
General/Family Practice	8.7	7.9	3.2	3.2
Medical Specialties	14.1	10.6	8.4	7.2
Surgical Specialties	17.1	11.6	10.9	8.5
Hospital Specialties**	4.9	4.1	3.4	3.2
Total***	49.8	37.3	28.8	24.6

Source: American Hospital Association 1982 Annual Survey

*Includes only active and associate medical staff members.
**Hospital specialists include anesthesiologists, radiologists, and pathologists.
***Includes other specialties not reported separately.

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The AMA Center for Health Policy Research directs the Socioeconomic Monitoring System in cooperation with the AMA Division of Survey and Data Resources.

hospitals. In 1982, proprietary hospitals had an average of 49.8 medical staff per 100 beds compared to 37.3 medical staff per 100 beds in nonproprietary hospitals. This difference in medical staffing patterns persists even when examining board-certified medical staff. Proprietary hospitals have, on average, 17 percent more board-certified physicians per 100 hospital beds than do nonproprietary hospitals—28.8 per 100 beds compared to 24.6 per 100 beds, respectively.

Analyzing the data by specialty reveals that differences in staffing patterns between proprietary and nonproprietary hospitals are greatest for the surgical specialties. Proprietary hospitals have 17.1 surgical specialists per 100 beds compared to 11.6 for nonproprietary hospitals. Only for board-certified general/family practice and hospital specialties do proprietary and nonproprietary hospitals have similar medical staffing patterns.

Influence of Hospital Ownership on Physician Practice Behavior

Concern about the role of profit in medicine has focused on the impact of proprietary hospitals on physician practice behavior. This section uses AMA first quarter 1984 SMS data to examine the influence of hospital ownership on physicians' practice patterns and behavior.

Data analyzed but not shown in the tables indicate that approximately 13 percent of all physicians with admitting or medical staff privileges are primarily affiliated with a proprietary hospital. However, many physicians have admitting or medical staff privileges at more than one hospital. On average, our evidence shows that physicians whose primary hospital is nonproprietary have privileges at 2.2 hospitals. Alternatively, physicians in proprietary hospitals have privileges at 2.8 hospitals.

Taking multiple privileges into account changes one's perception about the extent of physician involvement with proprietary hospitals. Of those physicians whose primary admitting hospital is nonproprietary, 11.9 percent also admit patients to at least one proprietary hospital. *As a result, one out of every four physicians with hospital privileges has some contact with the proprietary hospital sector.*

Table 2 reports information on hospital programs that are intended to monitor and influence physicians' practice behavior. In general, it appears that nonproprietary hospitals are more likely to establish programs for reducing and reviewing the length of patient stay than proprietary hospitals. For example, 71.8 percent of physicians with their primary privileges in nonproprietary hospitals report that their hospital has set guidelines to reduce the length of a patient's stay. Only 65.9 percent of physicians with their primary privileges in proprietary hospitals report that their hospital has set such guidelines. However, data collected but not reported in Table 2 indicate that proprietary hospitals were more active in implementing new hospital utilization review programs during 1983 than nonproprietary hospitals.

For those physicians who indicate that their hospital has set guidelines to reduce the length of patient stay, nonproprietary hospitals appear more likely than proprietary hospitals to restrict physicians' clinical discretion. For example, Table 2 indicates that 41.1 percent of the physicians with their primary privileges in nonproprietary hospitals indicate that their hospital has attempted to reduce the number of diagnostic tests they order compared to 39.8 percent of the physicians in proprietary hospitals. Furthermore, physicians in nonproprietary hospitals indicate that their hospital is more likely to have attempted to reduce the number of treatment procedures prescribed and the number of services offered than their counterparts in nonproprietary hospitals. However, these differences appear to be small.

In summary, the evidence presented in this report indicates that concerns raised about the role of investor-owned hospitals in influencing the practice of medicine may be overstated. This report finds that proprietary hospitals, on average, have larger medical staffs and board-certified medical staff per 100 beds than nonproprietary hospitals. Moreover, it does not appear that proprietary hospital ownership, compared to nonproprietary ownership, has adversely restricted physicians' clinical discretion. Physicians at proprietary hospitals are somewhat less likely to report that their hospital has guidelines on length of stay or a length of stay review program. They are, however, somewhat more likely to indicate that their hospital reviews physicians' clinical decisions.

Table 2

HOSPITAL INFLUENCE ON THE PRACTICE OF MEDICINE BY TYPE OF HOSPITAL OWNERSHIP

	Proprietary Hospitals	*Nonproprietary Hospitals*
Does hospital set guidelines to reduce length of stay	65.9	71.8
Does hospital review length of stay after discharge	84.9	90.1
Does hospital formally review clinical decisions	83.0	79.8
If the hospital has set guidelines to reduce the length of stay:		
Has the hospital attempted to reduce the number of diagnostic tests you order	39.8	41.1
Has the hospital attempted to reduce the number of treatment procedures you prescribe	26.7	32.2
Has the hospital reduced the range of services it provides	6.7	9.5

Source: American Medical Association, First Quarter 1984 Socioeconomic Monitoring System.

The President's Page

Divide and Conquer

The most basic stratagem used in any confrontation involving groups of people is to divide them thus making conquest or at least subservience significantly easier. Over the past twenty or more years we have seen this strategy applied either consciously or unconsciously to the medical profession under the guise that some nobler end will be achieved with more control of physicians.

Many lofty ventures which were conceived, nurtured and brought to fruition by physicians have been lost either through internal squabbling, self interest or the abrogation of our responsibility to the organization we founded. The best example of this in Connecticut has been Blue Cross/Blue Shield which was founded by physicians and which now has become a mutual company capable of writing types of insurance other than health. There now is minimal input by the medical profession into the activities of this organization and at times one gets the impression that the hierarchy of this company would indeed like to control the practice of medicine as well as our relationships with our patients. In fact, all third parties are tending in this direction without regard either for individuality on the part of physicians or quality of patient care.

Since the mid-sixties additional programs have been instituted by government and other third party payors without significant physician participation in the formulation of these programs. When it became apparent in recent years that health care costs were burgeoning and that it might be difficult for payors to fulfil their promises, a steady influx of new schemes was introduced and where government is concerned, were mandated. Among these have been PSRO, second opinion programs, mandatory second opinions in order to obtain full payment for elective surgery, HMO/IPA and more recently DRG'S, PPO'S, All-Payors legislation and PRO'S. Fortunately, the alphabet has not, as yet, been exhausted. All of these programs have primarily been concerned with cost containment and pay little regard to quality of care. At best, these programs have achieved only limited success in their primary aim but they have succeeded in dividing the members of our profession.

With the advent of the more avant-garde programs such as preferred provider organizations (PPO'S) and the application of reimbursement for services in physicians offices under DRG'S, the divide and conquer strategy will be in place because these programs go to an aspect of medicine, other than patient care, namely economics. The incentive for relinquishing one's individuality as a member of our profession will be short term economic gain. One needs to look no further than north of our border to see the results of this strategy in action. I urge all physicians to familiarize themselves with all programs being offered or mandated, ponder the effects of these programs on their own future and the future of new doctors before deciding on a course of action based on short term gain. Only through unity of purpose and active participation in organized medicine can the average practitioner have some influence and input into his manner of practice. We should not permit anyone to "Divide and Conquer."

Joseph S. Sadowski, M.D.
President

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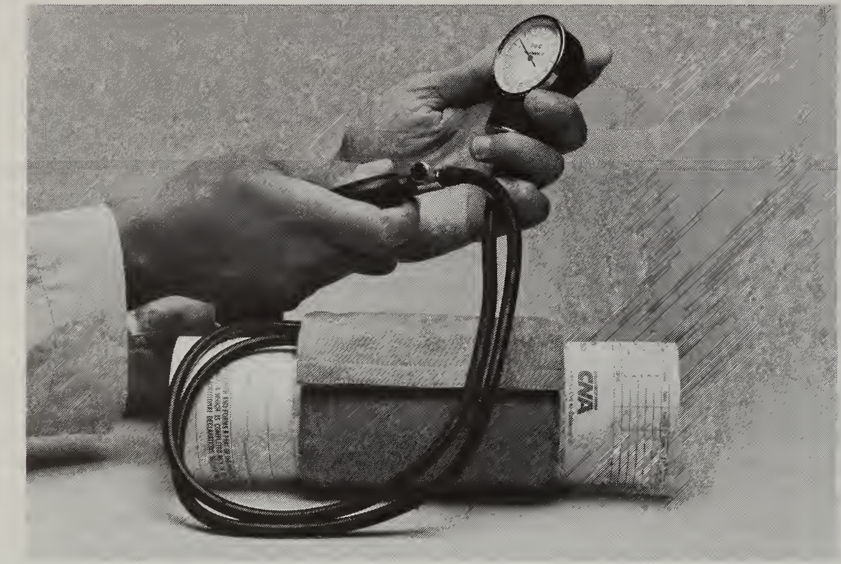

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Reflections From The Dean's Office

The Urge to Reform

ROBERT U. MASSEY, M.D.

Education is by its nature conservative; it is the undertaking by which the older generation tells the younger, "This is what we know, this is what we think is important, this is how we do things." Our fashions, our attitudes, our politics, our values, our scientific paradigms, and certainly our technology are rarely still for a moment but are always surging or swaying in unpredictable winds. Education requires stability: teachers, curricula, textbooks, standards, buildings, and equipment. It must therefore always be out of phase, and the stormier the times, the greater the tensions between society and its schools.

After the wars of religion in the 17th century, learning became more secular, emphasizing classical studies and extolling reason; in the 19th century with the rise of science, technology, industry, and trade, classicism went out, and the aim was toward practical learning.

> "I disagree with my late Father on this point," the Consul said. "I have always objected to the perpetual occupation of young heads with Greek and Latin. When there are so many other important subjects, necessary as a preparation for the practical affairs of life—"

In this piece of conversation from "Buddenbrooks," the Consul, a 19th century businessman, was taking a fairly typical 19th century position on education; his father had been an Enlightenment man from the 18th century.

We all recall Sputnik and all that followed, especially in the high schools and colleges: there were reforms and talk of reforms, but enthusiasm is hard to sustain, and the energy soon runs out. Our institutions are not immune from the Second Law, and 25 years later we had mostly forgotten Sputnik, until a decline in our favorable trade balance and in our children's SAT scores reawakened our uneasiness about the quality of our schools.

Medical education, in this country under recurring urges to reform since the mid-19th century, has now clearly entered a period *Sturm und Drang* from which it will emerge substantially changed. The signs are all around.

Elsewhere in this issue of *Connecticut Medicine* there appears a reprinting of "The President's Report, 1982-1983," by Derek Bok, President of Harvard University. This is a remarkably lucid summary, balanced and complete, of the forces which have led to the present reforming urge among medical educators, concluding with some suggestions about the direction in which this movement is likely to go. The report is remarkable in that the President of Harvard has devoted his entire annual report to the subject of medical education. As a lawyer he has avoided being censorious in his remarks; as a university president he has avoided being defensive. "Like ancient China," he noted, "medical education has experienced many assaults from the outside world without undergoing substantial change. Even so, I believe that pressures have now reached such a point that basic reforms are likely to occur."

Medical schools, or academic medical centers, have, especially in recent years, leaned heavily upon their faculties, full time, part time, and voluntary, for their support. In the heyday of biomedical research support from the NIH, faculty members were selected and rewarded for their ability to compete successfully for research grants; today, more and more, they are selected and rewarded for their ability to compete successfully for patients and referrals. Education gets left out of the reward system in either case; it is believed to be an assured by-product of research and patient care, something achieved mostly by indirection, bound to take place where scientists, scholarly clinicians, residents, students, and patients are all together in the same place. Indeed, it is often such a by-product, but it is by no means an assured one. There are worries about the preparation for medical school, about goals, about the content of the curriculum, about the teaching, about the outcome and how it should be measured—a kind of discontent with the entire business afflicting not just a few who are always discontented but almost everyone from students to trustees.

We do well, however, to remind ourselves that dissatisfaction with a task so weighty, so near the heart, is very likely inevitable. In 1910 William H. Welch wrote:

> "It is impossible to impart the entire content of medical and surgical science to the student. One cannot even impart the content of a single subject of the curriculum. The utmost to be expected is to give the student a fair knowledge of the principles of the fundamental subjects of medicine, and a power to use the instruments and methods of his profession; to give him the right attitude—"[1]

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ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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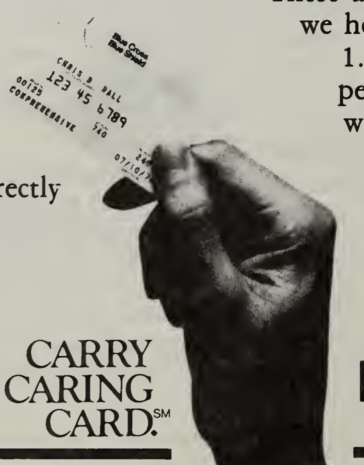

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Deciding for the Incompetent Patient: Identifying the Role of Family Members

JOSEPH M. HEALEY, J.D.

One very troublesome issue for contemporary health care practitioners involves determining how and by whom treatment and non-treatment decisions should be made for patients incapable of making their own decisions. In general, the anglo-american legal system presumes that those who reach the age of majority (usually 18) are legally competent to make decisions for themselves. If questions arise concerning the competence of a specific individual, those who raise such questions have the burden of establishing in court that the person is incompetent and that a surrogate (generally called a guardian or conservator) should be appointed by the court to make decisions for the incompetent person. Under a strict application of the law, no third party (including a family member) has the automatic legal authority to make decisions for the incompetent person unless the declaration of incompetence and the appointment of a surrogate have taken place. Such a view raises significant practical problems and concerns. An increasingly large number of patients appear to be unable to make decisions for themselves. Must a court-appointed surrogate be sought in every case? When close family is available and willing to participate as surrogates for their relatives, must the physician insist on prior court designation? These issues have begun to attract the attention of the courts. In my last column, I described a recent Florida Supreme Court decision addressing them. In this month's column, the discussion will continue.

In the Florida case,[1] the trial court had held that in the case of a comatose and terminally ill individual, in order to avoid potential criminal and civil liability for termination of life support systems under the facts of the case, appointment of a guardian to act on the incompetent patient's behalf, the filing of a petition for authority to order termination, and court approval were required. These cases, the trial court concluded, must be decided by the courts on a case-by-case basis. The Appeals Court affirmed the trial court decision agreeing on the need for court approval of the appointment of a surrogate. The Supreme Court of Florida rejected the lower courts' decisions, expanding the role of family members:

> "We hold that the right of a patient, who is in an irreversibly comatose and essentially vegetative state to refuse extraordinary life-sustaining measures, may be exercised either by his or her close family members or by a guardian of the person of the patient appointed by the court. If there are close family members such as the patient's spouse, adult children, or parents, who are willing to exercise this right on behalf of the patient, there is no requirement that a guardian be judicially appointed. However, before either a close family member or legal guardian may exercise the patient's right, the primary treating physician must certify that the patient is in a permanent vegetative state and that there is no reasonable prospect that the patient will regain cognitive brain function and that his existence is being sustained only through the use of extraordinary life-sustaining measures. This certification should be concurred in by at least two other physicians with specialties relevant to the patient's condition.
>
> The decision to terminate artificial life supports is a decision that normally should be made in the patient-doctor-family relationship. Doctors, in consultation with close family members are in the best position to make these decisions. The focal point of such decisions should be whether there is a reasonable medical expectation of the patient's return to a cognitive life as distinguished from the forced continuance of a vegetative existence."[2]

The language of the Florida Supreme Court's decision is very similar to the language of a recent Connecticut Superior Court decision in the case of *Foody v. Manchester Memorial Hospital:*[3]

> "Where (1) the incapable patient's condition is permanent and irreversible and there is no reasonable medical probability that the patient ever will return to a cognitive state, (2) the patient's attending physician together with at least two other consulting physicians unanimously concur as to the patient's condition, and (3) there are concerned family members who in good faith wish to exercise through substitute decision making the patient's right to discontinue artificial life-support systems, it is our conclusion that the family lawfully may act as the patient's substitute decision maker and may decide to discontinue the use of the respirator and we so hold."[4]

Though the *Foody* case was not appealed to the Connecticut Supreme Court and, hence, has limited precedential value, it represents a well-reasoned analysis of these issues and provides a good foundation for the development of Connecticut public policy in this area. In both cases, a critical question is the extent to which family members without prior court approval may serve as surrogate decision makers for incapacitated patients. On the one hand, there is a legitimate concern that allowing family members to make such decisions without prior court appointment will increase the risk that the rights of the patient will be violated. On the other hand, requiring family members to seek court appointment in all cases will increase the financial and emotional burdens of the family.

In my next column, I will conclude this discussion by describing two current proposals for seeking a middle ground.

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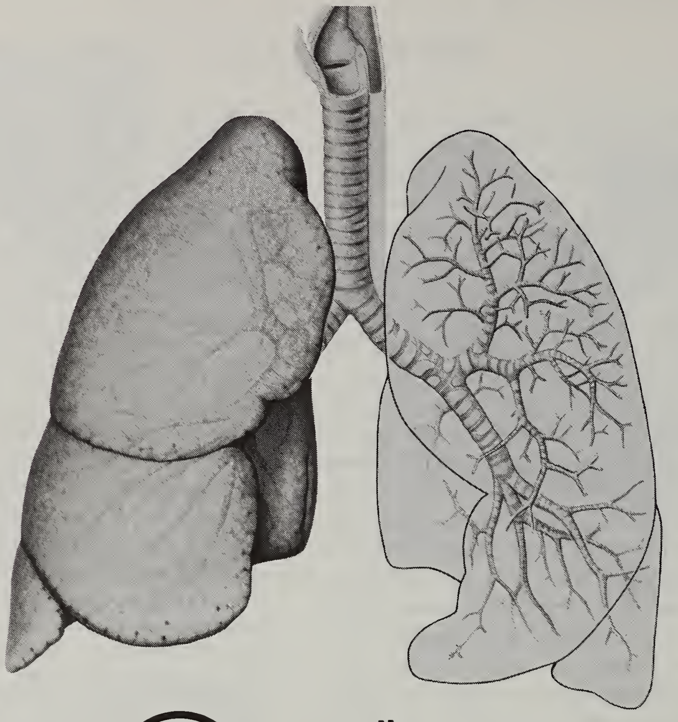
JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

Consider the causative organisms...



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Indications and Usage: Ceclor® (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae)*, *Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor.

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: *General Precautions* — If an allergic reaction to Ceclor® (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy — Pregnancy Category B — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor® (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below:

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbiliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

Note: Ceclor® (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Editorials

New Roles For Cardiac Rehabilitation

The New Britain Cardiac Rehabilitation Program—the longest running hospital-related program in Connecticut—has recently celebrated its first decade with a birthday party and the accompanying symposium. Each paper reflects long experience with secondary prevention, and the hopes of experienced practitioners for future developments. Two related and intriguing ideas concern the physiology of exercise therapy, and its role in the care of the sick cardiac.

For many years, the typical cardiac rehabilitation participant was a sturdy, middle-aged male with an adequate left ventricle. Since 1975, however, a growing number of patients with badly damaged left ventricles and other severe manifestations of ischemic heart disease has joined Phase IIIA of our program. Phase IIIA participants perform isotonic exercise of light to moderate intensity under the careful supervision of the cardiovascular nurse and exercise physiologist. Cardiovascular conditioning results both from central changes and from improved peripheral oxygen extraction. The physiologic goal of Phase IIIA is to condition the peripheral musculature and thus ease the load on the damaged ventricle. Several of our patients have shown significant improvement on exercise testing despite low left ventricular ejection fractions (LVEF). A recent example is a man of 35 years with LVEF of 26% whose maximum oxygen uptake has improved from 3 to 7 METS during the past year of therapy.

We have relied on observations that conditioning after infarction is not dependent upon changes in LV function;[1] that LV resting dysfunction does not necessarily predict exercise capacity;[2] and that patients' safety during exertion does not relate to LVEF.[3] Conn[4] has validated our clinical experiences, observing improved exercise capacity and oxygen pulse in ten patients with LVEF ranging from 13 to 26% (mean 20%). These findings lead us and Foster[5] to exercise our more disabled patients in the expectation of significantly improving their functional capacity.

An exciting new application of our rehabilitation service is the skilled surveillance of these sicker patients. Croog[6] points out the brevity and infrequency of patient contacts with their physicians following MI. Such brief contacts are likely to be suboptimal for modifying health behaviors; they may also deprive physician and patient of sufficient opportunity to observe progress or deterioration. Increasing numbers of patients are referred to us for surveillance in Phase IIIA. Some with severe coronary disease are under consideration for cardiac revascularization, but do not presently have sufficient clinical indications. Others have poor left ventricular function, ventricular arrhythmias, partially-controlled hypertension, or abnormal blood pressure responses to exertion which suggest dangerous ischemia. By means of the frequent ongoing contacts during exercise sessions, our cardiac rehabilitation nurses have helped us to identify patients who require changes in drug or other therapy. In several instances, observations of abnormal exercise performance have provided essential evidence of the need for coronary bypass surgery.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself responsible for statements made by any contributor.

Thus, a lengthening experience has taught us that the cardiac rehabilitation facility, if thoughtfully utilized, can and should function as the agent of physicians in caring for their most disabled patients; and as their eyes and ears in following therapy and in making difficult therapeutic decisions.

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Physician Assistants in Connecticut

On the 12th anniversary of the Yale Physician Associate Program, and almost the 20th anniversary of the Physician Assistant concept in the United States, Kohlhepp et al, brings us up-to-date on the status of the P.A. programs, especially in Connecticut.

From its initial development at Duke University as a program to develop physician extenders, and at Yale where the focus was on development of specialists in trauma, the P.A. program has emerged as a broad-based two-year program to develop qualified participants in the health care system. The course of study has become reasonably standardized and includes participation in basic science courses and clinical apprenticeships. In addition, certification to be a Physician Assistant, based on a National Board of Medical Examiners test, is included in the state requirements for licensure. Both have contributed to establishing standardized credentials for this new health care profession.

The P.A. has gradually gained acceptance among a significant number of practitioners both in private practice and in a hospital setting, but the final role and impact they will have on the health care system has not been clearly defined. Advocates argue that the P.A. has the ability to contribute to health care at reduced cost and at the same time improve the service rendered to patients. In addition they argue that the Physician Assistant is willing to practice in underserved areas, especially in rural and inner city settings. The extent to which these goals have been or will be achieved has yet to be subjected to critical review.

Although the P.A. is trained to be a generalist it seems clear from the article that an increasing number of graduates of Physician Assistant programs are seeking specialty practices within a hospital setting or are offering special services in the practice setting. My prediction is that this trend will continue for it offers the P.A. and the health care system an admirable cooperative arrangement. The P.A. trained for specialty practice, such as hemodialysis, chemotherapy, nutrition, patient education or house officer status, makes an important contribution to health care that is non-competitive with practicing physicians. Cost effectiveness and increased quality of care are both an integral part of this approach. The Physician Assistant and the physician gain mutual respect for each other's competence and there is no competition for patient's preference.

The Physician Assistant students coming into the program are an interesting and exciting group. Selected after baccalaureate training and at least one or two years of experience in health related fields they come to the program with maturity and dedication. Concern that the P.A. applicant is a frustrated applicant to medical school or was using the Physician Assistant program as an alternate route to medical school has not been observed. The percentage of P.A. students that goes on to medical school is very small and a survey of P.A.s reveals that they are quite happy and content in their current role. Equally important is the impressive degree of satisfaction that those who have employed the Physician Assistant have indicated. As mentioned in the article the overwhelming percentage of physicians would continue to employ Physician Assistants in the future. This combination of mutual respect and satisfaction bodes well for the future of the Physician Assistant concept.

Howard Levitin, M.D.

Dr. Howard Levitin is Dean of Students
and Professor of Medicine at the Yale University
School of Medicine. He is also Medical Director
of the Physician Associate Program at Yale.

Physicians and Government Affairs: A Call for Involvement

In "The President's Page" which appeared in the July issue of *Connecticut Medicine,* Joseph S. Sadowski, M.D., president of the Connecticut State Medical Society, made the observation that, when it comes to exerting influence at the State Capitol, the voice of physicians stands mute in comparison to that of other interest groups. As a former state legislator for 10 years (1970-1980) and as vice president, government relations for the Connecticut Hospital Association (CHA) for the past five, I strongly agree.

As a former legislator, I know how puzzled our state representatives and state senators are at times by the lack of involvement by physicians in governmental affairs, especially given the large impact which such matters can have on medical and patient care services.

This year, for example, the Legislature passed a bill to create what is known as an "all-payor/prospective payment" system for hospitals in this state, to be phased in over a two-year period beginning October 1985. While the exact details of how this system will work have yet to be developed, it is known that goal will be to reduce the size of increases in hospital expenditures by having hospitals do more to influence physician decisions regarding which patients are admitted for care, which tests are ordered, what types of care patients should receive, etc.

In short, the goal of this new law is to radically alter the way medicine is practiced in this state.

Despite this fact, however, only a small handful of doctors ever voiced an opinion to their local legislator on the bill or wrote him/her a letter. Indeed, it appears few even bothered to read the bill so as to form an opinion in the first place. "Consumers," incidentally, flooded the State Capitol with copies of medical and hospital bills, pleading for legislators to freeze the spiraling costs of medical care and health insurance. As a result, the Legislature was able to ignore the sporadic messages of the few physicians who did choose to act and to pass this measure into law so that now, not only will it impact on every hospital and practicing physician in the state, but on every hospital patient as well.

My own experience as a legislator confirms that this lack of participation in government affairs by physicians is nothing new. Many legislators would testify that physicians seldom contribute to political campaigns; have contempt for all things political especially politicians; write few letters (many of which are negative, emotional diatribes), and are patronizing, aloof and condescending. In addition, many physicians seem to subscribe to the fallacy held by others that insulting politicians is the best way to win the day in whatever legislative battle is currently underway. The most notorious example of this last point is physician reaction to talk of a state income tax.

Change in how physicians participate in the political process is no longer an option—it is a necessity. No lobbying effort of any consequence can work unless it is backed by a strong "grassroots" constituency statewide. That means physicians who have been apathetic or indifferent to political realities in the past, or who, worse, have used insults as a way to express their opinions, must learn to change their ways.

After 15 years of dealing with legislators on a daily basis at the State Capitol, there are many recommendations I could offer to the medical profession to assist them in uplifting their message from its present day howl. Perhaps the foremost is also the most obvious and least observed: Join in and become a part of the political process; meet with your legislators, discuss with them the various aspects of the high cost of health care and, most importantly, be willing to listen to what they have to say. Deal with issues that are current and relevant to today's concerns. Recently, for example, I heard one physician give a long, nonproductive harangue about how Medicare should have never been created in the first place because all it did was provide for a "drinks-are-on-the-house" mentality with regard to medical care. Whether or not there is one iota of truth in this view, it is clearly "water under the bridge" and irrelevant to any discussion about the decisions facing us now.

So meet with your legislators from time to time in a nonhostile, informal setting and explain to them in a civil way your concerns about the essential nature of health care services to patients. Ask them to strive for some reasonable balance between the hysteria that now seems to have gripped the public regarding cost and the need to continue to provide lifesaving services to our state's citizens without rationing. Above all, talk to legislators about patient needs and the impact proposed legislation will have on them.

When carried out in a proper and respectful manner, this approach enables each legislator to champion pro-medicine views and to be able to defend his or her actions to the legislator's various constituencies. They cannot do that now without the involvement of physicians in a rational and productive way.

Joseph S. Coatsworth

Vice President,
Connecticut Hospital Association

Guidelines for the Implementation of Peer Review Activities in Connecticut

The Connecticut Hospital Association supports the Connecticut Peer Review Organization (CPRO) as the most acceptable organization in Connecticut to implement the peer review program mandated by Public Law 97-248. CHA encourages its members to strive to assure that institutional health care services are medically necessary, conform to appropriate professional standards and are delivered in the most effective, efficient and economical manner.

Due to the unsettled conditions surrounding utilization review, quality assurance, "per case" payment systems and the implementation of Public Law 97-248, CHA should take a leadership role in developing a peer review oversight committee under CHA auspices with the following functions; monitoring of CPRO activities; development of quality/medical review criteria; evaluation of CPRO outcomes; act as an intermediary in the waiver and denial of claims process; provide continuing education and information to physicians about CPRO activities.

Furthermore, the Association has noted that other organizations, i.e., Department of Income Maintenance, health maintenance organizations and individual employers, among others, are developing and marketing their own utilization review programs which may further complicate the situation and increase hospital costs.

The Association suggests that its members pursue the following guidelines in their relationships with all elements within the peer review system:

GUIDELINE 1:

It is suggested that all inpatients, regardless of payor, be included in the review process in order to insure a quality assurance or quality assessment viewpoint. This would include not only the major governmental third parties but also encompass review for Blue Cross, commercial insurance, HMO, self-pay patients and others.

GUIDELINE 2:

CHA members are encouraged to support a single review mechanism for all patients. In order to establish the most efficient and equitable review system, hospitals should support those proposed review processes which are identical to the system established by the CPRO for the state. This guideline would apply to patients financed by the state, Blue Cross, commercial insurance, HMO's and individual employers.

GUIDELINE 3:

The hospital governing board through its medical staff is responsible for the quality of care provided within its institution. Hospitals therefore, should seek delegation from the CPRO to do the maximum amount of review possible within their own medical staff and administrative structure. All mandated hospital review costs should be recognized and paid for in any financing system established by third party payors.

GUIDELINE 4:

Hospitals statewide, should strive to implement a uniform preadmission certification program in order to minimize retrospective claim denials. This program would help hospitals when the prospective payment system in the state is fully implemented.

GUIDELINE 5:

An appeals mechanism which is sensitive to the needs and demands of the patient and his family, the physician, the hospital, and third party payors should be established to resolve problems on an individual case by case basis. An independent hospital organization should serve as the vehicle and advocate for a hospital's appeal from an adverse decision of the CPRO.

GUIDELINE 6:

A waiver process must be performed in a fair and equitable fashion. Denial of payment, within the waiver process, should be designed to change behavior through educational means and not through punitive measures.

GUIDELINE 7:

Continuing education programs should be provided for appropriate hospital personnel and hospital staff physicians regarding their respective roles in utilization review activities as they affect the hospital.

GUIDELINE 8:

Members should support the Connecticut Health Information Management and Exchange Program (CHIME) as the most appropriate data base to provide common statewide CPRO data requirements.

These guidelines were approved by the CHA Board of Trustees on May 14, 1984. They were prepared by an ad hoc committee chaired by David Parke, M.D., a member of the CHA board, and constitute an update of a set of guidelines adopted by the board in 1975 pertaining to PSRO activities.

The purpose of the guidelines is to clarify, for the benefit of the membership and other interested parties, the posture of the Association relative to the new Connecticut Peer Review Organization and utilization review activities, in general.

—Dennis P. May, President

Connecticut Hospital Association

FROM THE EXECUTIVE DIRECTOR'S OFFICE

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CALL
SEMI-ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1984 Annual Meeting of the House of Delegates will be held at the Sheraton-Bridgeport Hotel, Bridgeport commencing at 12:30 P.M. on Thursday, November 15.

Joseph S. Sadowski, M.D.
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INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides:

Resolutions may be introduced by any Active or Life Member or student members or postgraduate physician members of the Society, in compliance with the following provisions:

a. All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.

b. Component county associations or the student members or postgraduate physician members, whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.

c. Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business..

d. Any business which does not qualify as regular business in accordance with the foregoing provisons may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.

MARK YOUR CALENDAR

Connecticut State Medical Society
Semi-Annual Meeting—House of Delegates

Thursday, November 15, 1984

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Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult INFORMATION FOR AUTHORS. This material may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:

J. Alfred Fabro, M.D., Editor
Connecticut Medicine
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POST-GRADUATE NYU Medical Center MEDICAL SCHOOL

WINTER COURSE SCHEDULE

DECEMBER

12/3-6	350. Neurosurgery NYC/1984 (Grand Hyatt)
12/3-7	314. Toxicology and Pharmacology
12/10-12	321. Managing Clinical Problems in the Elderly
12/17-22	603. Computed Tomography (Grand Hyatt)
12/15-16	733. Basic Review of Pathology and Radiology for Urologists

JANUARY

1/9-6/26/85	302. Internal Medicine Board Review Wednesdays 4:00 to 7:00pm

MARCH

3/11-15	321b. Managing Clinical Problems in the Elderly (Cerromar Beach Hotel, Puerto Rico)
3/11-15	603b. Computed Tomography (Cerromar Beach Hotel)
3/18-22	304. Seminar in Advanced Rheumatology
3/25-29	100. Anesthesiology Board Review IV
3/30-31	735. Lasers in Urology

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PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

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PHYSICIANS WISHING TO PRACTICE IN CONNECTICUT

ALLERGY

July '84. Age 33. Nat'l bds. AB elig. MD, University of Rochester, Rochester, NY; Int., Res. and Fellowship, Children's Hospital of Buffalo, Buffalo, NY. Available for any type practice. Write, Christopher Randolph, M.D., 307 Summer St., Buffalo, NY 14233.

INTERNAL MEDICINE

July '84. Age 56. Licensed in Connecticut. Nat'l bds. AB cert. (PSY); elig. (IM); MD, NYU—Bellevue Medical School; Int. and Res. (IM), Greenwich Hospital, Greenwich, CT and Metropolitan Hospital, NYC; Res., (Psychiatry), Metropolitan Hospital, NYC. Prefers group type practice in a small community. Write, Peter B. Schneidau, M.D., 17A Appletree Lane, Darien, CT 06820.

Aug. '84. Age 28. AB cert. MD, Universidad LaSalle, (Mexico City); Int. and Res., Sinai Hospital, Baltimore, MD. Desires group, associate or institutional type practice. Write Eduardo Anhalt, M.D., 6A Spring Rock Rd., Branford, CT 06405.

July '85. Age 28. Nat'l bds. AB elig. D.O., NJ School of Osteopathic Medicine, NJ; Int. and Res., John F. Kennedy Memorial Hospital, Stratford, NJ; Fellowship, New Jersey Medical School Affiliated Hospital. Has a chief interest in critical care units. Desires solo or associate type practice in a small to medium-sized community. Write, Robert L. Werner, D.O., 148 Reservoir Rd., Parsippany, NJ 07054.

July '85. Age 28. Nat'l bds. AB elig. MD, University of Medicine and Dentistry of New Jersey Medical School, Newark, NJ; Int. and Res., Geisinger Medical Center, Danville, PA. Prefers a group or associate type practice in a medium-sized community. Write, William R. Betz, M.D., Ridgeview Eastlawn, Box 122, Danville, PA 17821.

July '85. Age 28. Licensed in Connecticut. Nat'l bds. AB elig. MD, S.U.N.Y. at Buffalo, NY; Int. and Res., University of Connecticut Health Center, Farmington, CT. Primarily interested in office based practice (group or assoc.) in a small to medium-sized community. Write, Roger J. Beneitone, M.D., 17 Arnold Way, West Hartford, CT 06119.

GASTROENTEROLOGY. July '85. Age 30. Nat'l bds. AB cert. MD, Mount Sinai School of Medicine, New York, NY; Int. and Res., Beth Israel Medical Center, New York, NY; Fellowship, North Shore University Hospital, Manhasset, NY. Prefers group or associate type practice in a medium to large-sized community. Write, Clifford J. Appel, M.D., 10 Wooleys Lane, Apt. 1C, Great Neck, NY 11023.

GASTROENTEROLOGY. July '85. Age 29. Nat'l bds. AB cert. MD, Albany Medical College; Int. and Res., NYU-Bellevue Medical Center, NY; Fellowship, Montefiore Hospital and Medical Center, Bronx, NY. Prefers group or associate type practice. Write, Henry J. Katz, M.D., 20 Waterside Plaza, New York, NY 10010.

PULMONARY. Sept. '84. Age 32. Presently in practice. Nat'l bds. AB cert. MD, Hahnemann Medical College, Philadelphia, PA; Int. and Res., Allegheny General Hospital, Pittsburgh, PA; Fellowship, Maricopa County General Hospital, Phoenix, AZ. Prefers multispecialty or pulmonary group preferred. Write, Jeffrey Ratner, M.D., 21 Palomino Lane, Bedford, NH 03102.

PULMONARY. July '85. Age 29. Licensed in Connecticut. Nat'l bds. AB cert. MD, S.U.N.Y. at Buffalo, NY. Int. and Res., Danbury Hospital, Danbury, CT; Fellowship, University of Connecticut/New Britain General Hospital, New Britain, CT. Prefers group or institutional type practice in a large-sized community. Write, Joseph A. Harrison, M.D., 343 Hampton Court, Newington, CT 06111.

OBSTETRICS/GYNECOLOGY

July '85. Age. 26. Nat'l bds. AB cert. MD, Hahnemann University, Philadelphia, PA; Int., St. Raphael's Hospital, New Haven, CT; Res., Danbury Hospital, Danbury, CT. Seeking to join a group or associate type practice. Write, Les A. Burns, M.D., 6 Essex Court, Brookfield, CT 06804.

July '85. Age 35. FLEX. AB elig. MD, Universidad Autonoma De Guadalajara, Guadalajara, Mexico; Int. and Res. SUNY Upstate Medical Center, Syracuse, NY. Trained in endocrine infertility and oncology laser surgery. Prefers group or associate type practice. Write, Amnon Fein, M.D., 223 East Ave., Apt. 6B, Syracuse, NY 13224.

Immediately available. Age 37. AB elig. MD, University of Bombay, India; Int., B.Y.L. Nair Hospital, Bombay; Res., Long Island College Hospital, Brooklyn, NY; Fellowship, Michael Reese Hospital, Chicago, IL. Trained in microsurgery, infertility, hysteroscopy and semen banking. Prefers solo, group, associate or institutional type practice. Write, Sheth Atul, M.D., 2951 King Drive, Chicago, IL 60616.

ORTHOPEDICS/SPORTS MEDICINE

July '84. Age 35. Nat'l bds. AB elig. MD, Georgetown University School of Medicine; Int. and Res., St. Lukes/Columbia University College of Physicians and Surgeons, New York City, (General Surgery); Mt. Sinai Hospital, New York City (Orthopedics); Fellowship, Cincinatti Sports Medicine. Prefers solo, group, associate or institutional type practice. Write, George McGinniss, M.D., 105 5th Ave. #8E, New York, NY 10003.

PEDIATRICS

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July '84. Age 36. Nat'l bds. AB elig. MD, Medical University of South Carolina; Int., St. Vincent's Hospital, NY; Res., St. Vincent's Hospital and Bronx-Lebanon Hospital Center, NY. Prefers solo, group or associate type practice. Write, Barry G. Jordan, M.D., 260 Garth Rd., Scarsdale, NY 10583.

UROLOGY

Immediately available. Age 31. MD, Autonomous University, Guadalajara, Mexico; Int. and Res., Downstate Medical Center, Brooklyn, NY; and Long Island Jewish Hospital, New Hyde Park, NY. Prefers solo or group type practice. Write, Edward C. White, M.D., 5 Starlight Court, Babylon, NY 11704.

Breast Cancer: Are Preoperative Bone Scans Necessary?

STEVEN HAZELRIGG, M.D.

Introduction

The approach to the treatment of patients with locally invasive as opposed to systemically invasive breast cancer differs significantly and as such it remains important to accurately stage these patients preoperatively. It has been noted that radical surgery is often ineffective with 30-40% of patients[20] undergoing radical mastectomy dying within five years, presumably because of occult metastasis present at the time of surgery.

Bone is the most common and earliest site of distant metastasis in breast cancer[21-23] with greater than 70% of patients dying of breast cancer having autopsy evidence of osseous spread.[24] With these facts in mind, and the knowledge that bone scans have been shown to be a more sensitive indicator of osseous metastasis than conventional radiographs,[3, 9,4] we have reviewed our results of bone scans in patients with breast cancer in an attempt to more clearly define the indications for preoperative bone scans.

Methods

The records were reviewed retrospectively of all patients with primary breast cancers between January 1978 and December 1982 utilizing the Bridgeport Hospital Tumor Registry records. Those patients who had a previous breast primary in the contralateral breast were excluded from this study. Four-hundred-sixty-two patients were discovered of which 318 received bone scans either preoperatively or within one month post operatively. The records of these 318 patients formed the basis for this study.

Bone scans were all performed using Technitium 99 diphosphate. Scan reports were classified as positive if there was one or more areas of increased activity not typical of degenerative, arthritic, traumatic or other non malignant conditions. Scans were interpreted as negative if no increased activity was observed. Abnormal scans not initially clearly placed in either of the above categories were either considered positive or negative after clinical, historical, and radiologic evidence was reviewed. Abnormal scans found with solitary defects not confidently called malignant by the radiologist were further evaluated by tomograms or bone biopsy to elucidate its positivity or negativity.

Patients were staged according to the International Union against cancer and the American Joint Commission in Cancer Staging and End Results Reporting adopted TNM system using clinical as well as pathological data when available.

Stage I was classified as a mass less than 2 cms without histologic evidence of tumor in axillary nodes. When no nodes were available for examination, those patients who were clinically felt to be free of tumor in the axilla were also classified as Stage 1. Stage II included tumors 2-5 cm in size or those less than 2 cm with clinical or histological evidence of tumor involvement in axillary nodes. Stage III being those greater than 5 cm primaries or any fixed axillary nodes. Stage IV were those with distant metastasis, supra or infra-clavicular adenopathy, edema of ipsilateral arm, peau d'orange changes, skin ulceration or any satellite nodules about the same breast. Results of bone scans were not included when staging these patients.

Results

Of the 462 patients, 69% (318) received bone scans, either preop or within one month postop. There were 104 (33%) patients grouped in Stage I, 202 (44%) Stage II, 43 (13%) Stage III and 32 (10%) Stage IV.

There were only two positive scans of those patients in Stage I. This represents approximately 2% of all scans on patients in Stage 1. One of these patients was a 74-year-old post menopausal female who had a lumpectomy performed with no nodes available for examination. The second patient was a 60-year-old postmenopausal female who had presented because of bloody discharge from her nipple and was simultaneously found to have an infiltrating ductal carcinoma in the contralateral breast with an intraductal papilloma being found as the cause for her symptomatology.

In Stage II there were 139 patients of which 5 (3.6%) had positive scans. Of these five patients, four were

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STEVEN HAZELRIGG, M.D., Surgical Resident, Bridgeport Hospital, Bridgeport, CT.

This paper was presented at the First Annual Connecticut Residents' Symposium on Cancer as part of the 192nd Annual Meeting of the Connecticut State Medical Society held in Hartford, CT on May 10, 1984.

greater than 50 years of age with three having complaints referable to bone pain. Clinically four of these five were felt to have involved axillary nodes. Only two of these patients had nodal dissections and both of these showed histologic evidence of tumor involvement. One patient refused further surgical procedures and the remaining two patients did not have nodal dissection because of upgrading of stage after results of the bone scans were known. Of the 139 patients in Stage II, 79 were clinically or histologically felt to have axillary involvement and as noted four of these had positive bone scans. This represents a 5.1% positive bone scan rate for patient(s) with adenopathy in Stage II as compared to 1.7% for those not felt to have nodal involvement.

Staged	*#Pts*	*#Scans*	*0 Scan*	*Pos Scan*	*Neg Scan*	*% Pos*
1	168	104	64	2	102	1.9
2	202	139	63	5	134	3.6
3	51	43	8	6	37	14.0
4	41	32	9	17	15	53.1

Discussion

Our results indicate that a low percentage of positive scans will be obtained for patients in Stages I & II. The percentage of positive scans for these patients in our study was 2.9% and of these patients 3 had complaints referable to bone pain. Thus very few asymptomatic patients were picked up by bone scan alone (1.6%).

The approximate cost of bone scans in our institution is $250/scan and this fee includes radiology reading fees. Thus each positive scan for patients in Stage I & II cost approximately $8500, and if only asymptomatic patients are considered the cost is slightly less than twice that figure.

Previously published literature provides a wide range of results with respect to the percentage of positive scans found in patients with early breast cancer. The relative high yield in Stage III patients however is generally agreed upon, and as such, bone scans should be performed in Stage III patients as a method of identifying those patients with distant metastasis. The results of various studies with respect to early breast cancer are shown in Table 1.

Our results correspond well with many of the studies but differ significantly from those Campbell et al, Hoffman & Marty, and Citrin et al. Some of the proposed reasons for these differences include:

differences in:

1. scanning techniques and sensitivities
2. incidence of axillary node involvement
3. length of time elapsed between operation and performance of scan patient population
4. criterion adopted for verification that abnormal scans actually represent carcinoma
5. clinical staging.

Hoffman & Marty had 60 patients referred to them for consideration of radiation therapy; some early staged patients had fixation to underlying pectoral fascia—which by TNM would be Stage III. Their study also included a high percentage of patients with axillary involvement.

Author(s)	*#Pts*	**Isotope*	*Staging System*	*Results (%)*
McNeil Et al (13) 1978 (Boston)	153	99mmTC	TNM	I-0 II-7%
Bishop Et al (14) 1979 (Nottingham)	354	99mmTC	Operable pts with primary lesions less than 5 cm without distant mets.	2.3%
Wilson Et al (12) 1979 (Michigan)	173	99mmTC	TNM	STAGE I-II 1.7%
Clark Et al (1) (Hartford)	201	99mTC	TNM	I-1.7% II-4%
Davies Et al (15) (Nottingham)	192	99mTC	Corresponds to TNM	I-II 5%
Strender Et al (16) 1981 (Stockholm)	387	99mTC	TNM	I-5% II-2.5%
Gerber Et al (8) 1977 (Naval)	122	99mTC	Correlates to I & II (histologically confined to breast-I Regional nodes involved-II)	I-2.7% II-0%
Baker Et al (2) 1977 (Johns Hopkins)	104	99mTC	TNM	I-4% II-0%
Campbell Et al (3) 1976 (Birmingham)	80	99TC	Manchester	I-18% II-41%
Citrin Et al (4) 1976	75	99mTC	TNM	I-12% II-19%
Hoffman & Marty (5) 1972	60	87Sr	I-medial or subareolar II-Pos. ax. nodes	I-20% II-38%

Campbell utilized the Manchester staging system which does not take into account the size of the primary if confined to the breast.

Studies have reported the yield of bone scans to be significantly higher in patients with axillary nodal involvement.[13, 3, 15] Davies et al noted a very low (approx. 2%) pick-up rate among patients with no nodal disease or only low axillary involvement as compared to 16% of patients with more extensive disease with respect to positive bone scans. Our study would tend to support this with 5.1% incidence of positive scans in Stage II patients with adenopathy vs. 1.7% for those without nodal involvement.

Studies have shown a greater tendency towards disseminated disease and worse prognosis for patients with positive scans[2, 3, 10] and it has been implied by Campbell et al that postmenopausal females have a higher rate of positive bone scans.

Despite the low yields there are several arguments put forth to support the use of bone scans as a screening procedure in all patients with breast cancer. These include the observation that even though the yield may be small, it may save those patients with positive bone scans a mutilating procedure to the breast. The point is also made that the initial scan may later serve as a very important baseline with which to compare repeat scans in follow-up. This may be important because a significant percentage of patients in early Stages (I-II) will later develop metastatic lesions. In a study by McNeil et al, 30% of those observed for a varying period of time up to 41 months had evidence of bony metastes with more frequent conversions in patient with Stage II & III disease than those in Stage I. Gerber suggested that followup with bone scans provided the best opportunity for early detection of recurrent breast cancer while Wilson et al stated that from preliminary evidence they had found that most recurrences were not found by bone scan but rather by patients complaining of pain over a stated area.

Another argument for routine scanning is that it may lead to early institution of radiation therapy, chemotherapy or hormonal therapy. To date there is no evidence that either the length or quality of life is enhanced by such early institution of treatment; further information with regard to this is needed.

In conclusion, our data coincide with several other studies in finding a relatively low yield from bone scans performed on patients with early breast cancer. With the ever present push towards cost effectiveness it becomes harder to justify its use for all patients. Our data would suggest that pre-op scans are indicated in all patients with a high level of clinical suspicion of metastases, symptoms of bone pain, or previous primary breast cancer on the contra lateral side. Our data do not seem to justify its use in asymptomatic patients in Stage I. The use of scans in larger lesions with adenopathy seems justified by other studies and all our Stage II patients who had positive scans had lesions greater than 2 cm with four out of five having clinical evidence of tumor involvement in the axillary nodes. Patients with Stage III disease have a high rate of positive scans and all these patients deserve a preop scan.

All abnormal scans should be correlated with routine x-rays of these suspicious areas and bone biopsy done if doubt as to their state of malignancy still remains.

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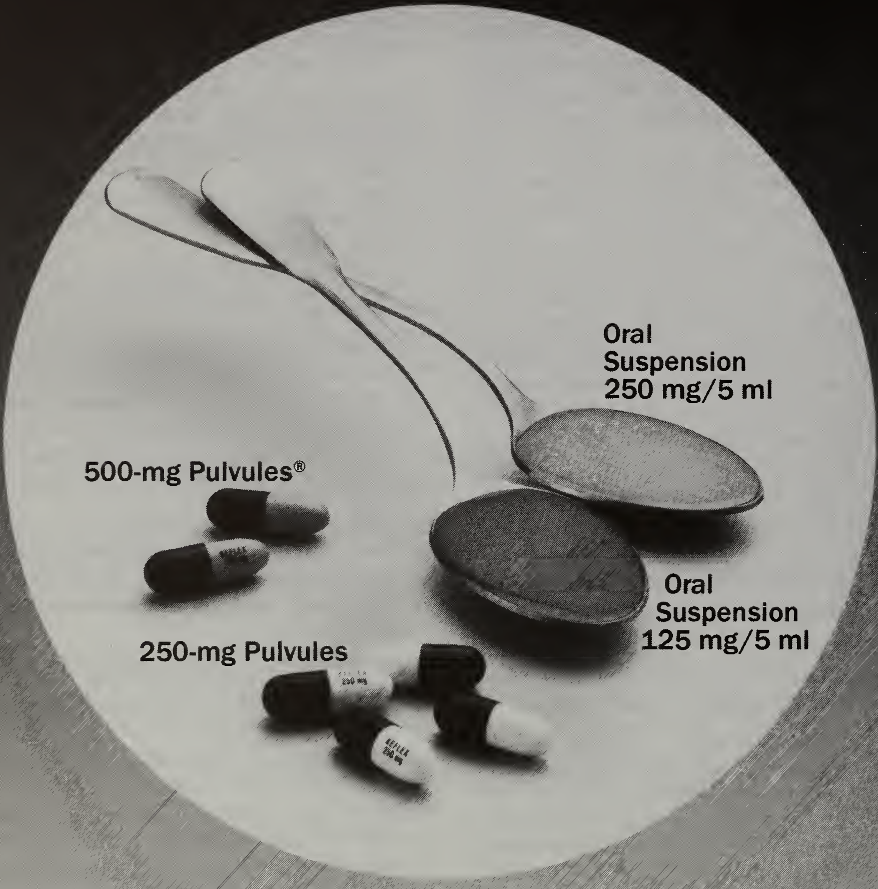

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Diagnosis and Treatment of Malignant Pericardial Effusion: The Subxiphoid Approach

K. BERMAN, M.D., L.P. FIELDING, M.B., AND A. AZIZ RICHI, M.D.

ABSTRACT—Pericardial effusions caused by malignant lesions are presenting for treatment more frequently (Prager et al. 1981). These patients are often admitted to the hospital in quite good general health, but their physical activity is severely restricted by poor cardiac performance in response to excercise.

Recently, we have treated three such patients, and in all the effects of the pericardial effusions were mitigated by draining the pericardial space using a subxiphoid approach.

We suggest that this method has four distinct advantages in comparison with the alternative methods by thoracotomy and transpleural approach or nonoperative pericardiocentesis.

1. It is safe under local anesthesia in even the most critically ill.
2. Tissue for diagnosis is possible without thoracotomy.
3. The technique effectively combines diagnosis and treatment.
4. None of our patients had a recurrence of the effusion.

Methods

We examined the case histories of three patients treated with the subxiphoid approach. We compared the morbidity, mortality, and length of efficacy of treatment with the numbers quoted for other methods. All the patients were followed up with echocardiography to evaluate the pericardium for reaccumulation of fluid.

Technique

The patients are prepped, and draped while awake so that the perixiphoid space may be seen clearly. Anesthesia is induced by either general or local techniques. A 10 centimeter incision is made from the xiphoid process towards the umbilicus. The linea alba is incised and the xiphoid tip removed. The distal sternum is elevated with a right angle retractor. The pericardiodiaphragmatic junction is identified. The diaphragm is retracted inferiorly while the pericardium is retracted superiorly. A 5 centimeter wedge of pericardium is removed. Cultures and tissues are sent for histology and pathology. Fluid is sent for cell block. The pericardium is visually inspected and carefully palpated. All loculations are broken up by blunt dissection using the fingers.

The pericardium is evacuated of all fluid. A tube (minimum 32 French) is inserted into the posterior pericardium and brought out through a separate stab wound. The incision is closed using nonabsorbable sutures. If the effusion is purulent, wire is used for closure. The subcutaneous tissue is left open. The tube is removed when the drainage has ceased.

Case Reports

Case 1: M.G.: A 21-year-old white male presenting with progressive shortness of breath, pleuritic chest pain, dyspnea on exertion, and 2-3 pillow orthopnea as well as a dry cough and anorexia. In the past he had had a gastrointestinal bleed of undetermined etiology at age 6. The physical examination revealed the following: jugular venous distention; distant heart sounds; decreased breath sounds at the right apex; and generalized pallor. A chest X-ray showed a right upper lobe infiltrate; tomograms confirmed a right upper lobe mass; an EKG was negative for ischemic changes; electrolytes, liver function tests, complete blood count, and urinalysis were normal. Echocardiogram showed a large posterior pericardial effusion.

A pericardial drainage by the subxiphoid approach was carried out. The patient did well postoperatively and exercise tolerance rapidly increased. The pathology of the pericardium revealed histocytic lymphoma.

The patient was discharged home on post-operative day 18. He continued to do well with a normal exercise tolerance. After three months the patient had an echocardiogram which showed *no* reaccumulation of the pericardial effusion.

Case 2: R.F.: A 75-year-old white female with severe cardiopulmonary disease, congestive heart failure, arteriosclerotic heart disease, diabetes, and a two-week history of progressive shortness of breath with dyspnea on exertion. In addition examination revealed a temperature (100 F) and mild respiratory distress, fundic changes consistent with diabetic retinopathy, jugular venous distention; decreased breath sounds at the right lower lobe; 2/6 systolic ejection murmur, hepatomegaly and pallor. White cell count was raised (26.3 cells per

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cubic millimeter). A pericardial tap cytology revealed malignant cells. Sputum was also positive for malignancy. An echocardiogram showed a large posterior pericardial effusion while a chest X-ray and tomograms revealed a right lower lobe mass and mediastinal node involvement.

The patient had a subxiphoid pericardial drainage. The cytology and pathology were consistent with bronchogenic carcinoma. Post-operatively, her excercise tolerance, appetite and general appearance markedly improved. She was discharged on post-operative day 25. She continued to do well after discharge and until her death at two months. A repeat echocardiogram one week prior to her demise showed *no* pericardial effusion.

Case 3: L.B.: A 73-year-old white female with a history of rheumatic fever, asymptomatic heart murmur, hypertension, and a hiatal hernia repair in 1981. Her post-operative recovery at that time was very slow. She did well until 3-1/2 months before admission when she had increasing shortness of breath and decreased appetite. On physical examination the jugular venous pressure was increased, heart sounds were distant, and the right lower lobe breath sounds were diminished. Chest X-ray revealed a globular heart and the echocardiogram demonstrated a large pericardial effusion. A pericardiocentesis was performed without resolution of symptoms and she then underwent a percardial window by the subxiphoid approach. Her relief and recovery were dramatic. Pathology revealed a pericardium studded with squamous cell carcinoma of the lung. She was discharged on post-operative day 18. She had a negative echocarciogram at 2-1/2 months post-operative and has continued to do well.

Summary

Of the three patients in our study two were female, all were Caucasian, and one expired within six months of diagnosis. The age range was 21-74 (mean = 55.3 years).

There was no morbidity or mortality referable to the operation. None had reaccumulation of their effusions as verified by post discharge echocardiograms. The average hospital stay was 20.3 days (range 10-33).

All patients had dramatic relief of symptoms with a rapid and complete restoration of normal exercise tolerances. In all three patients the pericardial drainage by the xiphoid approach provided the definitive diagnosis of malignancy.

Discussion

Pericardial effusion was first described in ancient times by Greek physicians; Galen, Pare, Morgagni, Lomar, and others have described this entity without a clear understanding as to its etiology (Spodick, 1970).

There are many causes for pericardial effusion in both the chronic and acute forms. This short paper has concerned itself with malignant pericardial disease (primary and secondary) but other causes include uremia, viral, tuberculous, collagen disease, and idiopathic pericarditis.

It is of historical interest to note that the subxiphoid approach was described 150 years ago by Larrey (Spodick, 1970) but it was only popularized 14 years ago by Fontanelle (Fontanelle, 1970).

The technique is simple and effective and can be performed under general or local anesthesia by both general surgeons and thoracic surgeons. The advantage of the local anesthesia approach is that it can be performed on the critically ill with minimum risk. The mortality and morbidity is low (zero in our small group of patients). While many patients are amenable to this approach, there are a few contraindications: obesity, constrictive pericarditis (documented by cardiac catherization) and a narrow perixiphoid space. The latter two problems allow inadequate exposure for excision of the pericardium.

Although patient survival may not be increased, and perhaps because the outlook is so poor any method must have a very low morbidity and mortality for it to be used in these patients. Thus it would seem that the anterior or transpleural approach is contraindicated and furthermore simple needle aspiration is usually ineffective and recurrence is highly likely. The technique described is safe and results have been dramatic and immediate and, furthermore, appear to be long standing.

Without cardiac compromise patients are more amenable to other methods of systemic chemotherapy for their underlying malignant condition.

Conclusions

The efficacy of drainage of pericardial effusions both malignant and nonmalignant is well documented. It is particularly useful in those with malignant pericardial effusions because it offers maximum palliation with minimal invasiveness.

The subxiphoid approach has four distinct advantages:

1. It is safe to do under local anesthesia even in critical patients.
2. More accurate diagnosis of the etiology of the effusion is possible.
3. Diagnosis and therapy are combined in one procedure.
4. The morbidity and mortality as well as recurrence are essentially zero.

Furthermore, the method is technically not difficult to perform and can be carried out by General and Thoracic Surgeons alike.

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The Treatment of Depression: Update 1984

BENNETT I. ENOWITCH, M.D., M.P.H.

The most common of the psychiatric disorders, depression comprises a heterogeneous group of disturbances properly called "affective disorders."

Most of the research in psychiatry today is focused on the area of depression. Thirty percent of articles appearing in psychiatric journals deal with some phase of affective illness. Three new antidepressants, aptly called the "second generation" of antidepressant drugs, have been introduced within the past four years. A fourth drug is scheduled for introduction in the United States in 1984. In Europe, some 20 different antidepressants are already on the market.

The purpose of this review is to present current thinking concerning the epidemiology of depression, the biochemical factors involved, and various treatment modalities that are being used in an attempt to reduce the suffering from this prevalent illness. It is not meant to be an exhaustive review, but rather a selective sampling that might whet one's appetite for further exploration.

The Prevalence of Depression

Weissman and Myers[1] in their 1978 paper found that, in the United States population, the probability factor within a lifetime for the occurrence of a major depressive disorder was 18% (12.3% in males and 25.8% in females). All studies show that unipolar depression is twice as common in women as in men (Clayton).[2] The average age range of onset is the early 40's. Angst has shown that unipolar affective illness in follow-up studies of hospital populations occurs as only one episode in 5-15% of cases.[3] The mean number of episodes in unipolar depression is 5-6 (Angst).[4] There is some evidence that the relapse rate is higher and more frequent as age increases. Murphy[5] has shown that between 10-20% of all patients so diagnosed will have chronic manifestation.

In 1974, experts from the World Health Organization estimated the prevalency of depression to be 3% of the world population. At that time, this represented some 100,000,000 people. Sartorius[6] noted that this number most likely would increase, for four reasons:

1. The increase in life expectancy in most countries would cause an increase in the number of people with a risk for depression.
2. The quick and changing psychosocial environment would result in a full spectrum of stress situations.
3. There would be an increasing morbidity of patients with chronic illness; for example, cardiovascular, cerebral vascular, and other neurological disturbances. These chronic conditions show approximately a 20% incidence rate of depressive symptomatology.
4. The excessive consumption of medications such as neuroleptics, cortiosteroids, and oral contraceptives which, with continued use, can bring about a depressive condition.

The Biochemical Basis for Depression

For years many workers have believed that, in endogenous depression, there is a deficiency of norepinephrine and/or serotonin (Goodwin[7] and Bunny, Matussek,[8] Schildkraut,[9] van Praag).[10] Birkmayer[11] has proposed that there is an imbalance of both of the transmitters.

Treatment Modalities

TCA's

At one time it was thought that the TCA's (tricyclic antidepressants) were divided into two distinct groups: those which blocked the uptake of serotonin with little or no effect on norepinephrine uptake (the tertiary amine TCA's such as Imipramine, Amitriptyline, Doxepin, and Trimipramine) and those which blocked norepinephrine with little or no effect on serotonin uptake (the secondary amine compounds such as Nortriptyline, Protryptyline, and Desipramine). Therefore, workers thought serotonin-deficient depressions would respond to tertiary amine drugs, and norepinephrine-deficient depressions would respond to secondary amine antidepressants.

More recent data collected by Richelson[12] indicates that most of the antidepressants are more potent at block-

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ing uptake of norepinephrine than serotonin. The one exception in the United States is trazodone.

MAOI's

The second group of antidepressants, the monoamine oxidase inhibitors (referred to as MAOI's), form a heterogeneous group of drugs having in common the ability to block the enzyme monoamine oxidase in the brain and various organs. At present in this country, two are used extensively: Phenelzine (Nardil) and Tranylcypromine (Parnate). A third, Isocarboxazid (Marplan), is also available, but used less frequently. There appear to be two types of MAO enzyme systems, Type A and Type B. The three drugs inhibit both of them. The drugs Deprenyl and Clorgyline are investigational drugs. They are selective in their inhibitory actions and are now undergoing investigational studies.

Although much research is being done in the neurotransmitter receptor field, and new theories and receptors are being discussed, there still is no definite knowledge of the actual action of these drugs. Such receptors as adrenergic, dopamine, histamine (types 1 and 2), muscaronic, acetylcholine, and serotonin have been examined.

However, most of the reports have been confusing and difficult to interpret. It is also interesting to note that atypical new agents such as aprazolam, trazodone, and mianserin do not block amine uptake sites or receptors.

Current Status of Treatment Theories

We may say at this point that there is no single biochemical hypothesis that can account for the clinical actions of the antidepressant. Thus, the major problem with the pharmacology of the antidepressant lies in the following areas: Some 30% of cases respond poorly; toxicity may still be a concern, even with the newer "less toxic" agents; generalizations about therapeutic levels are uncertain; and there is no coherent biochemical theory for the actions of the drugs.

It has been shown that between 65-70% of endogenously depressed patients respond favorably to tricyclic antidepressants. This response will usually occur after four to six weeks' trial with therapeutic doses of the drug used.

The remaining 30-35% of nonresponding patients can now be treated by alternative methods. First, however, compliance in taking the drug must be ascertained, by detailed questioning of both the patient and family members. A careful record should be kept of the number of pills taken as well as times during the day and evening the medication was taken.

If compliance is assured, it is then imperative to ascertain whether any physical illness is present that may be simulating a depression. Drug-plasma levels should be checked. Imipramine levels have been shown in many studies to have a direct correlation with recovery from depression. It is generally agreed that a blood level of 300 ng/ml is usually needed for a therapeutic effect with imipramine. This can, in most cases, be accomplished by taking 150-200 mg of the drug per diem.[13]

MAOI's have no therapeutic blood levels as such. However, platelet MAO inhibition is used. It is usually thought that 80% inhibition is necessary for MAOI effectiveness.

The next step in the case of the nonresponsive patient is to consider *higher dosage.* Assuming that serial EKG's show no abnormality, the imipramine dosage may be increased to 400-450 mg per diem. A 10-to-14-day trial should be allowed, with careful monitoring of both the psychological and physical sequelae.[14]

Ayd (1981)[15] and Rabkin, Hem and Quitkin[16] have indicated that, instead of utilizing trials with other TCA's, it is more efficacious to try other options with the nonresponsive patients.

Methylphenidate (Ritalin) HCL or Amphetamine (Dexedrine) Supplement: It has been observed that the addition of 5 mg to 15 mg of amphetamine to a TCA can convert a partial or minimal responder to a complete response. Ritalin (Methylphenidate), 10 mg, may bring the same response. If this regimen is going to prove effective, the patient will usually show response within one week. If a positive response occurs, then a two- to three-week continuation of the drug is warranted before the cessation of the methylphenidate or amphetamine. Longer use of these two drugs is to be avoided because possible addiction and/or dependency can develop. However, the possibility of a positive response from this brief drug encounter is worth the minimal risk involved. It has been estimated that two to four percent of partial or nonresponders will convert from a dysphoric mood with this method. The mechanism is still unclear.

L-Triiodothyronine (T3) Supplementation: Rabkin[17] and workers have pointed out that, in a study of five uncontrolled trials, between 64% and 90% of nonresponding TCA patients did indeed respond to T_3 supplementation. Goodwin[18] and others in 1982 reported on 12 patients who were either minimal responders or nonresponders to TCA. These patients showed an adequate drug compliance and had blood levels within the therapeutic range.

The TCA's involved were either imipramine or amitriptyline. Ten patients were given a T_3 supplement of 25 mcg per diem and two patients were given 50 mcg per diem to T_3. Sixty-five percent showed considerable improvement and one showed mild improvement. Improvement began within three days and side effects were minimal.

Therefore, it is advisable to add between 25 mcg and 30 mcg of T_3 to a TCA regimen of 300 mg.[19] A five-day trial is suggested. If responsive, the patient should remain on this supplement for four weeks, and then it should be discontinued. Cessation here should be more gradual with completion in five days. The mechanism is thought to be one of synergism of the two drugs.

Lithium Supplementation: DeMontigny[20] and workers in 1981 have shown that adding a supplementation of Lithium Carbonate to 300 mg of TCA has a beneficial effect for some nonresponding TCA patients. The theoretical biochemical basis for this is supported by a number of animal studies, which show short-term use of Lithium Carbonate increases the efficiency of the serotonin system. DeMontigny added 900 mg of Lithium per diem to the daily 300 mg of TCA. Within 24 hours all eight of his depressed, nonresponsive patients responded by showing alleviation of their depressed symptoms. Improvements continued for up to one year of follow-up. This method is safe, fast, as well as effective. Again, if a one-week trial brings no improvement to nonresponders, the treatment trial should be terminated.

MAOI Nonresponders: The protocol with depressed patients who have not responded to the MAOI is as follows:

1. Increase dosage of phenelzine (Nardil) to as high as 120 mg per diem or Tranylcypromine (Parnate) to 75 mg per diem.
2. L-Tryptophan supplementation. Coppen[21] in a 1967 paper wrote of the effectiveness of L-Tryptophan in conjunction with antidepressants. The conversion to serotonin and the subsequent increased concentration of the neurotransmitter at the postsynaptic receptor is thought to be responsible for its effectiveness. L-Tryptophan is a precursor of serotonin, and it is thought that increases in serotonin are the result with added precursors.

Cole[22] in 1980 felt that the L-Tryptophan enhances the action of the MAOI's, but not the TCA's, with the exception of clomipramine (Anafranil). L-Tryptophan can cause side effects such as nausea and sleepiness. Two reports concerning this treatment modality have shown serious toxic effects (Baloh[23] in 1982 and Thomas and Rubin[24] in 1984). It has not been approved by the FDA.

Pyridoxine Supplementation: Several studies have revealed that depressed patients in general have lower pyridoxine levels than normal controls. Klein[25] in 1980 showed that depressed women taking oral contraceptives responded to taking pyridoxine. Depressed patients showing lowered vitamin B6 levels and unresponsive on their MAOI should have a pyridoxine trial. This technique appears to be harmless.

The Last Resort Attempt: Combined MAOI-TCA Therapy

Although the 1983 PDR clearly describes the potential hazards which may result from the combined use of MAOI and TCA therapy, Ayd[26] in 1982 indicated that during the past 20 years several thousand patients, mainly in England, were treated successfully with this modality. The greatest danger to health (convulsions, cerebral hemorrhage) is noted when a TCA is introduced after an MAOI has been given. Because of the risks, this method is reserved for TCA and MAOI refractory patients, for whom ECT is contraindicated or unsuccessful.

The usual procedure is to start with a TCA such as imipramine, amitryptyline, or doxepin 150 mg per diem, and after three days add Phenelzine 15 mg per diem. The dosage of these drugs is increased slowly every two to three days until a maximum of 200 mg of TCA and 60 mg of Phenelzine is reached.

Thus, there is a selection of options that may be attempted in the partially respondent patient and the totally refractory patient. Much more research with the second generation of antidepressants must still be done to ascertain if certain subgroups of depressed patients would be responsive to particular drugs. With these techniques, the rate of treatment success can be raised to about 85% of the depressed population. This is indeed an encouraging finding. It appears that a solid knowledge of the basic pharmacological action of antidepressants, together with the newer supplementation methods and refined nosological interaction, will allow for more accurate diagnosis and improved treatment success rate for this ubiquitous group of previously unresponsive depressed patients.

Infusion Technique

Kielholz[27] in Switzerland has developed a technique that is used to treat drug-resistant depressed patients. His method consists of an infusion technique utilizing two antidepressants, one that is a potent serotonin re-uptake blocker and one that is a potent norepinephrine blocker. The patient receives a mixture of these two drugs together with a saline solution for a 21-day period. The actual infusion takes approximately one and a half hours per day. His results have been promising in that he indicates a 60% cure rate in his previously drug-resistant patients.

Summary

In conclusion, we can see that, in 1984, we have a greater understanding of the biochemical implications that are involved in the etiology of depression. We also have an assortment of new pharmacological techniques that can reduce the suffering of a group of patients who do not respond to the use of antidepressant medication. These techniques are easy to use and have a very minimal potentiality for any untoward reactions. It behooves the clinician to have a knowledge of these methods.

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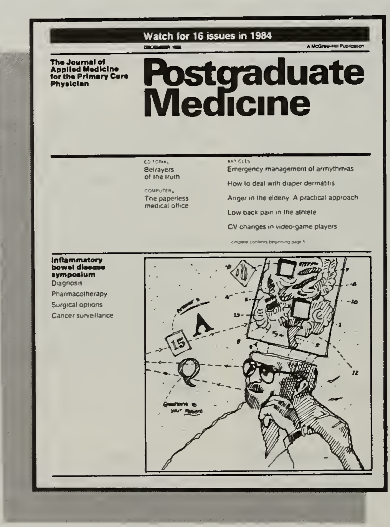

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Intravenous Biopsy of a Tumor Thrombus Filling the Inferior Vena Cava

PETER M. SHIMKIN, M.D., OCTAVIO G. CHOY, M.D.
AND A. THOMAS LICCIARDELLO, M.D.

Experience with transvenous biopsy of a tumor thrombus is limited, as the need for the procedure rarely arises. We adapted our technique of transjugular liver biopsy[1] to obtain suitable specimens from a renal cancer filling the inferior vena cava of a patient with a bleeding diathesis.

Case Report

A 57 year old, 300 pound male developed hematuria after being anticoagulated for ileo-femoral thrombo-phlebitis. Pyelography was normal except for diminished concentration of contrast material excreted from the right kidney. CT visualized a thrombus filling and distending the right renal vein and inferior vena cava but the origin of the presumed tumor was unclear. CT showed no metastatases in the brain or lungs.

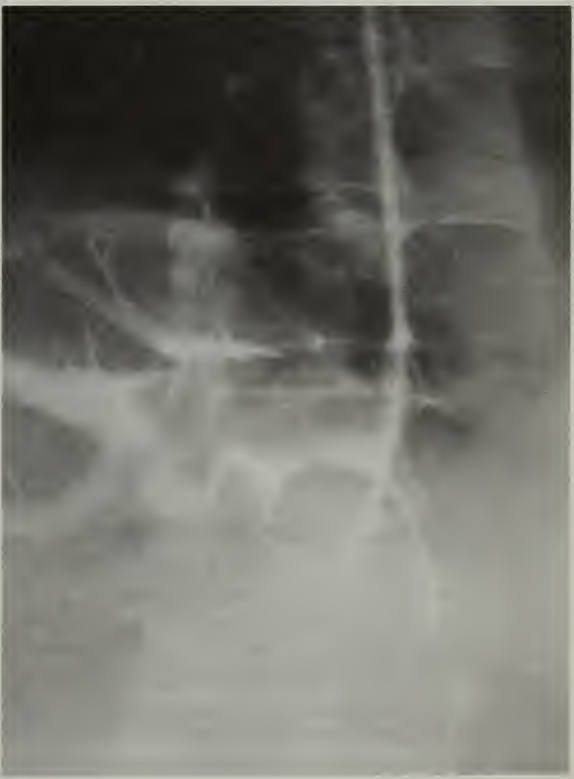
Anti-coagulation was discontinued, but the prothrombin time could not be corrected. The patient became febrile and increasingly lethargic. It was decided that a histologic diagnosis was essential: if the tumor were a lymphoma chemotherapy could be indicated. Because of the unexplained bleeding diathesis, an intravascular approach was considered the safest method for biopsy. The transjugular route was chosen after a right femoral venogram filled only the ascending lumbar system and a caval lumen could not be identified.

A 9F teflon catheter was inserted percutaneously into the right internal jugular vein and advanced under fluoroscopic control into the upper inferior vena cava until resistance was encountered. Test injection of contrast solution showed the catheter tip wedged against the cap of a thrombus (Figure 1).

A cytology specimen was obtained by passing a long, flexible 22g Hawkins cholangiographic needle[a] through the catheter 3cm. into the tumor. Continuous suction was applied to the needle hub during penetration of the mass and subsequent removal of the needle from the catheter. "Quick stain" of the aspirate disclosed undifferentiated malignant cells and subsequent examination of cell block material yielded a diagnosis of undifferentiated renal carcinoma.

The mass seemed firm and immovable upon insertion of the thin needle. This encouraged us to obtain a larger specimen. A 16 gauge modified Ross transeptal needle[b] was advanced through the catheter, thrust 2cm into the tumor and immediately removed from the catheter. As before, continuous suction on the needle hub was applied once the mass was entered. Three 6mm fragments thus obtained verified the histologic diagnosis of undifferentiated renal carcinoma.

The patient tolerated the procedure without discomfort or complications. He expired 6 days later of cardiac arrest. Autopsy disclosed disseminated renal carcinoma which filled the inferior vena cava. No pulmonary emboli were identified.



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[a] Cook Medical Products Catalogue DHWK-1

[b] Cook Medical Products Catalogue TJC-1

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Discussion

Many malignancies (e.g., lung, pancreas, breast) grow through and destroy the walls of veins. Other tumors, benign (e.g., chemodectomas) and malignant (most commonly renal cell or hepatocellular carcinoma) gain access to a vein starting within the organ and extend sometimes quite long distances within the lumen of the venous system. The patient may present with signs and symptoms referable to venous obstruction, such as the Budd-Chiari syndrome.[2]

The indications for transvenous biopsy of a tumor thrombus are the same as for transjugular liver biopsy: bleeding diathesis, marked ascites or obesity. Under these circumstances, the procedure is safer and more certain than percutaneous transperitoneal needle aspiration techniques. The main risk is producing a pulmonary embolus.[3]

Mills et al obtained positive cytologic specimens from 4 of 6 intracaval tumors by abraiding them with a 2cm. nylon bronchial brush inserted through an intravascular catheter.[3] We felt that thin needle aspiration was more certain of success. The "feel" of the tumor gained by the Hawkins needle also provided encouragement for use of the rigid Ross needle. This recovered a more generous tissue specimen than previously described methods which have used gastroscopic biopsy forceps passed through an intravascular sheath[4] or simple aspiration of an angiographic catheter wedged into the tumor.[5] We frequently obtain 2cm. cores during transjugular liver biopsy.

After removal of the Ross needle during transjugular liver biopsy tissue fragments may be retained in the indwelling catheter. Although this did not occur in our case, the angiographer should liberally aspirate the catheter to ensure that the entire sample is recovered.

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Important Advances in Clinical Medicine

Epitomes of Progress—Neurosurgery

The Scientific Board of the California Medical Association presents the following inventory of items of progress in neurosurgery. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in neurosurgery that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Neurosurgery of the California Medical Association and the summaries were prepared under its direction.

Management of Intraventricular Hemorrhage in Neonates

Intraventricular hemorrhage can occur in any neonate but premature infants are at greatest risk as the fetal brian contains a subependymal germinal matrix, a gelatinous structure that overlies the caudate nucleus and is separated from the ventricular system by only a single layer of ependymal cells. At term the matrix is but a remnant whereas in premature infants this structure is large. Intracranial hemorrhage is usually preceded by a hypoxic-ischemic insult and may be followed by destruction of neuronal and glial precursors in the germinal matrix, destruction of brain parenchyma and hydrocephalus to a varying degree, depending on the magnitude of the hemorrhage. The immediate management of a neonate with intracranial hemorrhage is directed toward maintaining adequate cerebral perfusion and preventing conditions that might lead to further extension of the hemorrhage—such as arterial hypertension, hypoxemia, hypercapnia, acidemia and rapid changes in blood volume and osmolality. Neruosurgical treatment is limited to the hydrocephalus. The effectiveness of various methods of treating hydrocephalus is somewhat unclear because, with relatively the same amount of blood in the ventricles and subarachnoid spaces, the hydrocephalus will resolve on its own in some cases where it will progress in others.

The initial treatment of posthemorrhagic hydrocephalus is with repeated lumbar puncture. If the hemorrhage produces obstruction between cerebrospinal fluid in the ventricles and that in the lumbar region, lumbar punctures will be ineffective and it will be necessary to control the hydrocephalus by removing fluid directly from the ventricles. One way to accomplish this is with repeated ventricular taps but at the expense of additive parenchymal damage. An alternative procedure is to insert a ventriculostomy, which allows cerebrospinal fluid to continuously drain externally. This method obviates the need for multiple ventricular punctures but can be cumbersome, require particular attention to detail in its management and be complicated by infection, obstruction and dislodgement.

Another approach is to place a subcutaneous ventricular catheter reservoir that can be intermittently tapped percutaneously to remove cerebrospinal fluid. The design of smaller, more pliable reservoirs has eliminated the problems of skin or wound breakdown for even the smallest of premature infants. The reservoir can be aspirated daily for months without infection. Obstruction of the reservoir has not proved to be a problem in spite of the fact that the fluid can be very bloody and has a high protein content. The reservoir is very rarely tapped more than once a day, the hydrocephalus being controlled instead by increasing the amount of cerebrospinal fluid aspirated at each tap. The major drawback to using the reservoir is that the removal of

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fluid is intermittent. It is not known whether the fluid buildup and concomitant rise in intracranial pressure between taps are detrimental; clinical experience indicates that this is not a significant factor. If the hydrocephalus does not resolve, the reservoir can be converted to a ventriculoperitoneal shunt without a valve as an elective procedure.

Apparently the outcome of infants who have intraventricular hemorrhage depends more on the degree of intraparenchymal hematoma than the extent of the ventricular clot or the degree of the ensuing hydrocephalus. Fortunately, a precipitous decline in the prevalence of severe intraventricular hemorrhage in preterm infants has been noted, the reasons for which are yet to be fully determined.

J. Gordon McComb, M.D.

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Central Nervous System *Taenia solium* Infestation (Cysticercosis)

Migration of persons from endemic areas is increasing the frequency with which central nervous system signs of infestation of the larvae of *Taenia solium* are encountered. Well-recognized manifestations include diffuse parenchymatous disease; calcified larval forms causing seizures; a basilar adhesive and racemose form, ventriculitis; intraparenchymatous disease with the formation of mass (cystic) lesions; intraventricular cysts, and spinal forms of both an inflammatory and a mass nature. The clinical manifestations include toxic encephalopathy with increased intracranial pressure, a focal neurologic deficit from intraparenchymatous disease, obstructive hydrocephalus from intraventricular disease or adhesive processes in the cerebrospinal fluid pathways, meningitis and spinal cord compression. These features may occur singly or in combination.

Diagnosis is based on probable epidemiologic exposure, historical and physical findings, radiologic studies—specifically, computed tomographic (CT) investigation—and serologic examination. Palliative surgical therapy is appropriate for the relief of hydrocephalus when this is produced by ventriculitis or an obliterative inflammatory process involving the apertures of the ventricular system or the basilar cisterns (or both) and rarely for the excision of mass lesions when they present as focally dangerous mass processes. Surgical "cure" of intraventricular cysts may be expected if these are the only manifestations of central nervous system disease and if all such lesions are removed. This requires direct access to the cysts, which may be encountered—singly or otherwise—in the lateral, third or fourth ventricle.

Recent advances in our understanding relate to the recognition of more limited clinical syndromes produced by the death of intraparenchymatous larval forms. Such involution is presumably due either to the natural immunocompetence of the body or to the use of pharmacologic agents, or both. The progress of focal intraparenchymatous disease can now be observed by sequential CT scan study and shows a feature of the infestation not heretofore generally recognized. Thus, in contrast to the often overwhelming manifestations of diffuse parenchymatous involvement, the same inflammatory process, but of a more limited and localized kind, is being observed. Clinically and radiologically this process progresses to death of the larvae with establishment of the calcified state and with a quieting of the severe antigenic response (probably akin to a Jarisch-Herxheimer reaction). Whereas the control of such acute inflammatory features may be achieved with steroid therapy, recurrence often occurs unless larvacidal drugs are used. The derivative of pyrazinoisoquinoline (praziquantel) is now being applied in Mexico, South America and sporadically in the United States. The drug is of low toxicity and in incompletely "controlled" clinical experience is reported to be sufficiently promising to urge its use for almost all forms except strictly intraventricular cystic disease or masses causing spinal cord compression. Surgical palliative treatment for other causes of hydrocephalus may still be required.

W. Eugene Stern, M.D.

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Computed Tomography of the Spine

X-ray computed tomography (CT) has become the most useful tool for diagnosing spinal, intraspinal and paraspinal pathologic conditions. The technically advanced equipment rapidly generates highly detailed images of bone and soft tissue, enabling a multitude of uses in congenital, traumatic, inflammatory, neoplastic and degenerative diseases.

With complex spinal deformities or extensive tumors, in addition to the primary axial images, secondary images reformatted in coronal, sagittal or oblique planes are often useful. Reformatted images are also used when scan sections must be obtained oblique to the axis of interest.

Injecting the myelographic contrast agent, metrizamide, into the cerebrospinal fluid continues to add new dimensions to CT. This water-soluble, nonionic, radiodense agent, used in CT in volumes and concentrations much lower than those necessary for plain-film metrizamide myelography, defines the subarachnoid space, fills root sleeves, outlines the cord, conus, roots and cauda and fills the hydrosyringomyelic cavity. Metrizamide CT is often used as an adjunct to plainfilm metrizamide myelography and in many instances replaces it.

The smaller doses of metrizamide CT produce significantly less morbidity, and newer agents with even fewer side effects are being developed. Low-dose metrizamide CT is gaining acceptance as an outpatient procedure.

In lumbar spondylosis and disc rupture, CT without the use of a contrast medium often produces diagnostic studies with more useful information than from conventional myelography; in many instances a surgical procedure for disc rupture or spinal stenosis is done on the basis of a CT diagnosis without myelography.

CT is routinely used in postlumbar disc operations (failed back surgery syndrome). Computed tomography is valuable in defining bony stenosis of the spinal canal, lateral recess or a neural foramen; however, differentiating between recurrent disc herniation and epidural scarring may be difficult and is controversial. Metrizamide definition of the subarachnoid space and root sleeves may help.

Intravenous administration of contrast media has limited usefulness. It may enhance visualization of epidural scar tissue and intraspinal tumors.

Nuclear magnetic resonance CT has proved valuable in the diagnosis of hydrosyringomyelia, spinal tumors and gross pathologic conditions of the cord, but at the current stage of development it is much less useful than x-ray CT in diagnosing most other spinal pathology.

Richard A. Yadley, M.D.

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Metastatic Tumors of the Spine

Symptomatic metastatic lesions of the spine develop in up to 14% of patients with malignant tumors. Such tumors most frequently arise in the lung, prostate, breast, kidney and thyroid and from lymphomas and multiple myeloma. The major presenting symptoms are spinal or radicular pain (or both), motor weakness, sensory loss and loss of sphincter control. Studies useful in establishing the diagnosis include plain spine x-ray films, radionuclide bone scanning, computed tomography and myelography.

For spinal metastasis limited to bone and producing only pain, radiotherapy and, where appropriate, chemotherapy constitute the treatment of choice. For lesions in the epidural space producing spinal cord compression, treatment is controversial. Traditionally these lesions have been treated with decompressive laminectomy followed by radiotherapy. Some recent reports suggest, however, that radiotherapy alone may be as effective as the combination of laminectomy and radiotherapy. High-dose systemic corticosteroids may produce dramatic relief of symptoms and are recommended for patients undergoing either irradiation or laminectomy.

A recent advance in the treatment of spinal epidural metastatic tumors involves resecting the vertebral body anteriorly and replacing it with acrylic. This approach often provides better tumor removal and spinal decompression than laminectomy because metastatic spinal lesions compressing the spinal cord or cauda equina often originate in the vertebral body and grow posteriorly. Anterior vertebral body resection and acrylic replacement also provide spinal stability rather than contributing to instability, as in the case of laminectomy.

Regardless of the form of therapy all authors agree that results are best when neurologic deficits are mild. Patients known to have cancer who complain of spinal or radicular pain, leg weakness or numbness or sphincter dysfunction should be assumed to be suffering from spinal metastasis. Aggressive radiologic investigation and prompt therapy are essential to prevent paraplegia.

Ronald F. Young, M.D.

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Locked-In Syndrome and Coma Vigil

One of history's most prolific authors, Alexandre Dumas, described in his classic story *The Count of Monte Cristo* (1844) a man made helpless by a paralytic stroke whose sole means of communication with his relatives, friends and visitors was the blinking of his eyes. His may have been the first description of the "locked-in syndrome," given more recent attention by Plum and Posner, who suggested the term, and by other authors. These locked-in patients have lost, through destruction of descending pathways in the brain stem—usually by vascular, traumatic or progessive degenerative mechanisms—the ability to initiate speech or extremity motion, while retaining a fully alert and responsive conscious state. They, like the character of Dumas, are in fact the wakeful and thinking prisoners of their bodies. A recently recognized cause of a motionless, "frozen" state with normal consciousness is the severe parkinsonian picture produced by substantia nigra cell destruction by one of the products of street drug manufacture, MPTP (1-methyl-4-phenyl-1,2,4,6-metrahydropyridine).

By contrast, patients with akinetic mutism, or its French synonym, coma vigil, have a clinical picture consisting of an apparently alert state, with open eyes following an examiner but without communication. Such patient's seeming wakefulness is illusory, and examination shows the absence of any suggestion of consciousness and no semblance of communication. They are, in fact, in coma, usually caused by extensive bilateral cerebral disease of traumatic, toxic, anoxic or vascular nature.

Clearly, the patients whose "de-efferented" state consists of the inability to interact with their environment while retaining mental function require careful and compassionate attention. Because they often retain spontaneous voluntary ocular motion, they can communicate with their surrounding world, if their unique and tragic state is recognized. Mechanisms of communication based on coded signals have been devised, and related approaches using sophisticated detection of fine ocular motion are in development. More direct systems based upon the detection of changing cortical electrical or blood-flow patterns may be predicted to be helpful in assuring return of some interaction with the intelligent world for these patients, but all such approaches will require the alert recognition of patients whose profound motor impairment causes an appearance of coma in the presence of a functioning but isolated mind.

Grant E. Gauger, M.D.

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Laser Applications in Neurosurgery

The use of lasers (*l*ight *a*mplification by the *s*timulated *e*mission of *r*adiation) for neurosurgical procedures has gained increased acceptance over the past three years. Presently three laser sources are being used for neurosurgical procedures: the carbon dioxide (CO_2) laser; the argon (Ar) laser; and the neodymium-yttrium-aluminum-garnet (Nd:YAG) laser.

The major advantage of laser sources is gained when they are used with a micromanipulator (to reduce physiologic tremor) connected to the operating microscope. This allows increased precision, a very gentle removal of tissue with the absence of mechanical deformation and varying degrees of hemostasis depending on the specific laser source used.

Lasers are most useful when the following criteria are present: (1) firm, nonaspiratable tumor consistency; (2) the lesion is in a critical area or in the motor-speech area of the brain; (3) the lesion is moderately vascular, and (4) the approach is narrow and instruments partially obscure the operative field.

The CO_2 and Ar lasers have been used to greatest advantage in removing extra-axial tumors such as acoustic neuroma, meningioma and the like, especially those in critical areas. Adapted to stereotaxic frames, they have been used to remove deep-seated intra-axial lesions. Their use for intra- and extra-axial spinal lesions has been similarly encouraging. The Nd:YAG laser has recently been used for removing moderately vascular tumors and vascular malformations. The recent development of an Nd:YAG micromanipulator will expand its applications to fine microsurgical procedures.

The Ar and CO_2 lasers have been used for neuroablative surgical procedures (such as those for dorsal root entry zone lesions, myelotomy, trigeminal tractotomy) and have decreased surgical morbidity. When the Ar laser is used to pump (stimulate) a dye laser, the red light produced has been used to activate a hematoporphyrin derivative to treat malignant neoplasms. The application of this therapy to brain tumors is under investigation at a few institutions such as the University of California at San Francisco, the Mayo Clinic and the University of Southern California.

Low-power, dedicated CO_2 lasers have been used to weld tissues—that is, to do microvascular and microneural anastomoses and tendon repair. Similar accomplishments have been achieved using the Ar and Nd:YAG lasers. Their clinical usefulness is under investigation.

Most recently lasers have been combined with fiberoptic endoscopes and angiographic catheters for vaporizing atherosclerosis in coronary and peripheral arterial vessels. The application of this new technology to cerebral vessels will be investigated in the near future.

In the next year, we will undoubtedly see new wavelengths introduced, each with its own specific application. Multilaser systems and the linking of lasers to computers for automated tissue removal, ultrasound depth-controlled lasers and new forms of delivery systems are potential advances. All of these innovations will increase the usefulness of lasers and improve our microneurosurgical techniques. Although the laser represents a technologic advance for neurosurgery, one must always keep in mind the adage "If you don't need a laser, don't use one."

Michael S.B. Edwards, M.D.
James E. Boggan, M.D.

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Spinal Infusion of Morphine for Pain

It is now five years since the first report appeared indicating that prolonged analgesia followed intrathecal morphine installation in cancer patients. This report was quickly followed by others relating the experience of analgesia with the epidural use of morphine and meperidine. These initial trials were based on earlier research—which has been reviewed—showing the action of spinal opiates at certain sites within the nervous system. The number of articles describing intraspinal narcotic use has rapidly expanded since these initial reports.

Postoperative pain has been treated with promising results; excellent and long-lasting relief of pain is provided and there is a concomitant reduction in the need for additional systemic analgesics. Significant advantages are conferred on a postoperative patient; analgesia is provided with a minimal narcotic effect, less central sedation occurs and pulmonary function is improved. Multiple side effects are known to occur, however, the most significant being possible respiratory depression. Monitoring of respiration for at least 24 hours following intraspinal narcotic administration, on an acute basis, is thus required.

Chronic pain syndromes have been treated in the same fashion; analgesia is unaccompanied by significant changes in motor function, sympathetic outflow or response to nonnoxious stimuli and apparently the risk of respiratory depression is very low. Patients with various malignant conditions have benefited from this technique.

Implantable devices designed to deliver the narcotics have been used; tolerance to continuous intrathecal infusion of morphine, however, has been noted. The best candidates for this procedure appear to be those patients with intractable pain below the diaphragm of malignant origin. Patients should respond to a test dose of intrathecally given morphine with at least six hours of pain relief. An intraspinal morphine preparation has been approved by the Food and Drug Administration and implantable reservoirs for continuous infusions of morphine are available. In the future, selective spinal antinociception will expand to other spinal receptor populations as we move to an era characterized by the delivery of multiple selective spinal agonists and antagonists of the central nervous system.

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When Should Intracranial Pressure Monitoring Be Used?

Intracranial pressure monitoring remains controversial and is not used consistently by neurosurgeons. Despite lack of actual proof of improved outcome due solely to intracranial pressure control, intracranial pressure monitoring nonetheless has strong advocates who cite anecdotal evidence for the importance of these techniques in some disease states.

Intracranial hypertension (usually defined as a pressure of 20 or 25 mm of mercury or more) has been shown repeatedly to correlate adversely with poor outcome from head injury. Most patients with traumatic coma and hemorrhagic abnormalities on computed tomographic (CT) scans have intracranial pressure elevations, which should be monitored and controlled if possible. In such comatose patients with normal initial findings on CT scans, intracranial hypertension rarely develops within 24 hours of injury but delayed CT abnormalities can develop and intracranial pressure can rise after the first day. Thus pressure monitoring should be considered for patients who remain comatose and whose CT scan findings become abnormal.

Neurologic dysfunction in Reye's syndrome, once thought to be almost uniformly fatal, usually is attended by increased intracranial pressure. While some permanent neurologic damage or even death can still occur with this toxic hepatoencephalopathy, brain injury probably arises from ischemia due to intracranial hypertension and often can be avoided by intracranial pressure monitoring and control.

In recent years monitoring of intracranial pressure has been used in a variety of neurosurgical patients. For patients undergoing craniotomy for lesions such as arteriovenous malformations, aneurysms or brain tumors in which the surgeon feels postoperative brain swelling may occur, intracranial pressure monitoring offers an important guide to therapy directed at ensuring optimal cerebral perfusion. Ventriculomegaly from cerebrospinal fluid outflow obstruction by hemorrhage or tumor can be treated by ventriculostomy and drainage; intracranial pressure monitoring via an intraventricular catheter can determine the amount of drainage required as well as resolving need for drainage. Permanent cerebrospinal fluid shunting can be avoided by this technique in some patients.

Iatrogenic barbiturate coma has been advocated in some types of brain injury such as trauma or focal ischemia, though the efficacy of this therapy is not yet

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proved. Because most neurologic function is severely depressed with this treatment, intracranial pressure monitoring is advocated to ensure that a progressive intracranial pathologic condition such as brain swelling or hematoma formation is detected and treated so that adequate cerebral perfusion is maintained.

The treatment of increased intracranial pressure has been discussed in detail elsewhere. Because there is some toxicity involved with these therapies, they should be used as sparingly as possible to maintain normal intracranial pressure. There is poor correlation with changes in the intracranial pressure and alterations in the neurologic state; intracranial pressure elevations can be detected earliest and best by pressure monitoring. Using current low-risk techniques for monitoring intracranial pressure, proper therapy in appropriate amounts can be administered to ensure adequate brain perfusion.

Lawrence H. Pitts, M.D.

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Computed Tomographic Guided Stereotaxis of the Brain

Computed tomographic (CT) imaging has enhanced the accuracy and safety of diagnosis and therapy in many provinces of medicine. The wedding of principles of stereotaxic neurosurgery and computed tomographic imaging has added an immediate new dimension to neurologic surgery and offers great potential for future innovation.

As opposed to CT-monitored techniques that commonly aid intracranial manipulation in the setting of a radiology suite, CT-guided stereotaxis allows selection of intracranial target points in a scanner, with minimal scan time (15 minutes or less). Target point data are then sent to a neurosurgical operating room, where the intracranial procedure may be undertaken in an advantageously flexible and familar setting with regard to instrumentation, sterility and skilled neurosurgical nursing personnel.

Using these techniques, it is now possible under local anesthesia to have direct and accurate access (within 1 mm) to any intracranial point (cerebrum, cerebellum or brain stem) without the need for craniotomy and with recovery times of less than six hours. Absolute diagnosis may be obtained for suspicious lesions by techniques that use 4-mm scalp incisions, 3-mm twist drill calvarial perforation and miniature conduits and instruments at a target point. Biopsy and culture material taken by the use of these techniques provides histologic and microbiologic data that allow logical direction of subsequent therapeutic strategies and circumvent the often nebulous nature of radiographic assessment and the attendant risks of major craniotomy.

With this technique several instruments can be used at the intracranial target point to accomplish several objectives, including retrieving tissue, draining fluid collections, evacuating hematomas or abscess debris, placing therapeutic radionuclides and taking a biopsy or excising certain circumscribed lesions using a miniature cerebroscopic device.

The technique provides a totally new perspective and alternative in the management of intracranial mass lesions, which will increase in sophistication and capability with developments in image data processing, instrumentation at the target point and adaptation to nuclear magnetic resonance and positron emission tomographic imaging.

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Effects of Minor Head Injury

Minor head injuries account for the admission to hospital of about 400,000 patients annually in the United States; the number of patients briefly rendered unconscious and not admitted to hospital is unknown and therefore the total cohort of persons at risk to suffer the residue of a minor head injury substantially exceeds those requiring hospital treatment. Minor head injury may be defined as a history of unconsciousness not exceeding 20 minutes, a Glasgow Coma Score of 13 to 15 and a hospital stay for not more than 48 hours. A small but significant percentage of those persons have cognitive-behavioral deficits that primarily involve reduced attention-concentration, impaired complex information-processing skills, increased irritability and memory problems. Negligible cognitive-behavioral sequelae were once thought to accompany minor head injuries and most patients with such trauma are discharged from hospitals with normal neurologic signs after observation. Those who have headaches, increased aniexty, emotional liability, concentration deficits and memory problems after a minor head injury are often stated to suffer from a "postconcussive syndrome," a syndrome thought to represent a psychologic disturbance rather than damage to neural tissue induced by trauma. Evidence for psychogenic determinants is not lacking but recent histologic, neurophysiologic and neuropsychologic data point to specific neuropathologic alterations associated with postconcussive symptoms in cases of minor trauma.

A mechanism proposed to account for neural damage and behavioral dysfunction in minor head injuries is shear-strain. This model suggests that acceleration-deceleration injuries result in axonal tearing and neural degeneration. Because 80% of all minor head injuries are related to vehicular accidents, falls and sports injuries, a model of shear-strain emphasizing acceleration-deceleration and rotational forces seems especially relevant to minor head trauma. Minor head injury is a multifactorial disorder and the outcome is related to many factors. For now, it is essential to recognize that mild head injury is an overlooked condition that may result in neuropsychologic dysfunction that necessitates intensive evaluation and treatment.

John A. Kusske, M.D.

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Chemonucleolysis

Chemonucleolysis refers to intradiscal therapy for herniation of the nucleus pulposus using a proteolytic enzyme. The concept of chemical dissolution of a nucleus pulposus dates back to the early 1950s. Various enzymes have been proposed; however, the drug in current clinical use is chymopapain, a proteolytic enzyme derived from papaya latex, which has an affinity for acid mucopolysaccharide occurring in the nucleus pulposus. Chemonucleolysis was first attempted in human beings in 1963 following earlier animal experiments using chymopapain given intravenously to rabbits. The ensuing two decades were marked by considerable controversy and debate concerning the safety, effectiveness and toxicity of proteolytic enzymes in intradiscal therapy. Following prolonged double-blind studies, chymopapain achieved approval by the Food and Drug Administration for clinical usage in November 1982.

Stringent clinical criteria for patient selection must be observed. The following indications for chemonucleolysis have been recommended: documented herniated nucleus pulposus with nerve root involvement, significant disability resulting from pain, and failure to respond to an adequate trial of conservative therapy (generally considered to be two to four weeks of bed rest). Chemonucleolysis at present has been approved for use only in adults and only in the lumbar area. It is not recommended as treatment for degenerative lumbar disc disease. Among the recognized contraindications are allergy to papaya derivatives, previous chemonucleolysis, previous lumbar disc surgery at the same interspace, rapid neurologic deterioration or the presence of other spinal pathology, such as spinal stenosis, spondylolisthesis and spinal cord tumors. Clinical findings and impressions should be confirmed by appropriate neurodiagnostic studies.

Chemonucleolysis in an operative procedure done in hospitals by surgeons who routinely manage lumbar disc problems, who possess training and current experience in disc surgery and who have received additional training in intradiscal therapy. The procedure is done either in the operating suite or the x-ray department under general or local anesthesia. Adequate x-ray facilities and anesthesia standby are essential. The patient is placed in a prone or lateral decubitus position and a long spinal needle is placed in the center of the nucleus pulposus under fluoroscopic control using a posterolateral approach. Discography is commonly carried out. Following a test dose, the definitive injection of chymopapain is made. The patient must be monitored carefully for several hours after the injection. Patients generally are discharged from hospital after several days of recuperation.

The results of chemonucleolysis are comparable to those of laminectomy and discectomy. Of properly selected patients, 70% obtain significant relief, though there is a 15% to 18% recurrence rate. It is of interest that of those patients who are not helped by chemonucleolysis, 90% are helped by subsequent laminectomy.

Anaphylactic reaction, a major deterrent to chemonucleolysis, occurs in about 1% of patients treated and results in a mortality rate of about 0.2%. Anaphylactic reaction seems to occur more frequently in women and in the presence of an elevated sedimentation rate. Preoperative treatment with corticosteroids and histamine blocking agents supplemented by adequate hydration has become commonplace. Other significant complications include chemical or bacterial discitis, mechanical injuries to the neural structures and inadvertent intrathecal injections.

In conclusion, chemonucleolysis is an operative procedure that is a viable alternative to lumbar laminectomy and discectomy for the treatment of documented herniated nucleus pulposus in carefully selected patients. It is not a panacea. Satisfactory results are directly related to proper patient selection. Some benefits of the procedure include minimal tissue disruption, shorter hospital stays, cost savings and better patient acceptance. With increasing clinical experience, there have been disappointing reports of poor results, prolonged severe back pain, prolonged hospital stay and a high incidence of recurrence necessitating further surgical treatment. A recent report by a manufacturer of chymopapain cites 21 cases of serious complications—paraplegia, cerebral hemorrhage and seizures—in 30,000 treated patients. It seems clear that the final chapters of chemonucleolysis remain to be written.

Philipp M. Lippe, M.D.

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State Societies Dues for the Year 1984

Below are the fifty-one State Societies in the order from the highest dues assessment down to the lowest:

1.	District of Columbia	$565.00
2.	Hawaii	465.00
3.	Wisconsin	445.00
4.	Minnesota	375.00
5.	Montana	370.00
6.	Maine	355.00
7.	Colorado	350.00
8.	Alaska	350.00
9.	Idaho	345.00
10.	Wyoming	300.00
11.	South Dakota	300.00
12.	Rhode Island	300.00
13.	Kentucky	300.00
14.	Arizona	300.00
15.	Washington	298.00
16.	California	290.00
17.	Utah	285.00
18.	Pennsylvania	275.00
19.	Oregon	275.00
20.	New Jersey	275.00
21.	Iowa	275.00
22.	Nebraska	265.00
23.	Michigan	260.00
24.	Illinois	253.00
25.	West Virginia	250.00
26.	North Dakota	250.00
27.	Maryland	250.00
28.	Mississippi	241.00
29.	Texas	235.00
30.	Louisiana	235.00
31.	New York	225.00
32.	New Hampshire	225.00
33.	Georgia	225.00
34.	Florida	225.00
35.	Arkansas	225.00
36.	South Carolina	220.00
37.	Massachusetts	220.00
38.	Oklahoma	210.00
39.	Indiana	206.00
40.	Delaware	205.00
41.	New Mexico	200.00
42.	Kansas	200.00
43.	Ohio	195.00
44.	North Carolina	190.00
45.	Vermont	185.00
46.	Nevada	180.00
47.	Connecticut	175.00
48.	Alabama	175.00
49.	Tennessee	170.00
50.	Virginia	150.00
51.	Missouri	135.00

BEHIND THE FACE OF HYPERTENSION

New evidence for central control

Removal of Life Support Systems

KEENETH FOODY, *ET AL.* : SUPERIOR COURT

VS. : JUDICIAL DISTRICT OF
HARTFORD-NEW BRITAIN

MANCHESTER MEMORIAL
HOSPITAL, *ET AL.* : MARCH 5, 1984

Memorandum of Decision

In this action, the Court is asked to enjoin all attending physicians and Manchester Memorial Hospital personnel from continuing the use of life-sustaining systems calculated to continue the respiration and pulse of Sandra Foody. Additionally the Court is asked to declare that discontinuation of such systems shall not subject the attending physicians and hospital personnel to civil or criminal liability.

Plaintiffs, Kenneth and Ann Foody, are the parents of Sandra Foody. The plaintiff, Kenneth Foody, is the conservator of the person of Sandra Foody. Sandra Foody is a forty-two year old patient at Manchester Memorial Hospital. On December 15, 1983, Sandra Foody suffered a respiratory arrest resulting in severe hypothermia. She was taken by ambulance to the emergency room of the hospital where she was successfully resuscitated and intubated. She was admitted and placed on a respirator. She is semicomatose, unable to breathe without the respirator. The relief requested will, according to the medical testimony, have a determinative effect upon the life of Sandra Foody; it will, with reasonable certainty, result in her death within a matter of minutes.

FACTS

I

Nature of the Proceedings

This matter comes before the Court by way of a hearing on plaintiffs' complaint on February 21, 1984. The named defendants are the Manchester Memorial Hospital, its acting executive director, Sandra Foody's attending physician, the attorney general for the State of Connecticut, the State's Attorney's office and Sandra Foody's guardian ad litem. The hearing covers both the temporary and permanent injunctive relief sought with the higher standard for the issuance of a permanent injunction governing the Court in its determination.

II

The Hearing

Based upon the evidence presented in this case, the Court makes the following findings concerning Sandra Foody's medical condition. For the past twenty-four years Sandra Foody has been diagnosed as suffering from multiple sclerosis. During that period the disease has become progressively severe, there have been no extended periods of remission. Her condition has steadily declined, she has not been spared by the plateaus sometimes associated with multiple sclerosis. Her balance and vision were first affected. Eventually she was confined to her bed or wheelchair. She lost control over her motor functions. She has been declared legally blind. By December of 1983, Sandra could not sit up on her own, nor hold her head up. She could not speak so that others could understand. She could swallow, and showed response to noise. By December 15, 1983 her breathing became heavy and she had been yawning increasingly. On that day she developed respiratory arrest, became cyanotic and was unable to breathe on her own. Her father dialed the local emergency number after unsuccessfully trying to reach the family physician. A policeman arrived and administered mouth to mouth resuscitation prior to the arrival of the ambulance. She was rushed to Manchester Memorial Hospital emergency room where she was successfully resuscitated and intubated by the hospital staff. After admission she was placed on a respirator. A tracheostomy was performed to avoid trachea collapse. A tube was placed through the opening formed by the tracheostomy which was attached to the respirator. The body's reaction to the tube was an increase in secretions which the force of the respirator caused to enter the lungs. These secretions must be removed from Sandra's lungs by suction catheter at least three to four times per nursing shift. She receives nutrients through a nasogastric tube.

Sandra's condition is stable. She is semicomatose. Attempts to trigger a breathing reflex have failed. She must be turned by the hospital staff to prevent the development of sores. Each time she is turned the respirator must be shut off. An electroencephalogram taken on February 17, 1984 indicates the presence of brain waves but the results are very abnormal. It is thought that only her brain stem is functional. The brain stem controls the heartbeat, body temperature and some reflexive action. Her gag and grimace reflexes are present. Deep tendon reflexes and plantar responses are absent. Her pupils are only sluggishly reactive to light. Her gaze is fixed downward and to the right with some change as the head is rotated. She has perceived sleep patterns. She cannot see and it is believed that she cannot hear. Her eyes blink randomly and involuntarily. Tests show that she has no pain response. In all medical probability she has no cognitive function, i.e., her brain is incapable of synthesizing and understanding outside stimuli. Her condition is best described as awake but unaware. Her semicomatose state is not believed to be attributable to multiple sclerosis, but to an aspiration while eating, which produced acute respiratory arrest, causing insufficient oxygen to the brain.

Having shown no sign of improvement after two months of treatment, Sandra's condition is considered to be permanent and irreversible. Generally, recovery of consciousness is very unlikely for patients with hypoxia who remain comatose or in persistent vegetative state for more than one month. *See Deciding to Forego Life-Sustaining Treatment, Ethical, Medical, and Legal Issues in Treatment Decisions,* President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, March, 1983, Pr 40.8:Et 3/L 62/2, P. 178-179 (hereinafter "Commission Report"). No diagnostic or therapeutic interventions are viewed as appropriate. The prognosis for improvement is considered hopeless. Sandra will require long-term care in a chronic care facility, connected to a respirator for the rest of her life. It is estimated that should the respirator be disconnected, brain death would occur after approximately ten minutes.

In addition to medical evidence, testimony was offered on the quality of Sandra's lifestyle prior to her being stricken with multiple sclerosis and the high degree of quality care which she received at home from her parents after the onset of the disease. Prior to her illness, Sandra was active in high school, playing in the school orchestra and working on the school newspaper. She was involved in scouting and church activities. After graduation she enrolled at Central Connecticut State College but withdrew after one semester due to her worsening health condition. After her eyesight failed she enjoyed talking book recordings and listening to the radio. During all the years of confinement with MS, she rarely cried and was known by her parents to have only once verbalized complaint, stating: "I have eyes but cannot see, I have legs but cannot walk." At no time has Sandra expressed an opinion on the use of extraordinary life support systems on patients with no reasonable hope of recovery.

Finally, it is notable that Sandra Foody has no material estate. Her medical expenses are borne by insurance and Title XIX. The coverage will not be exhausted. Her family, therefore, has no financial interest in the outcome of this proceeding.

LAW

I

Individual's Right to Control His Person

Plaintiffs urge the Court to authorize "the discontinuance of the extraordinary means being used" to maintain Sandra Foody's life. The legal basis offered for this request is the right to bodily self-determination.

The right to privacy, though not explicitly provided for in the Constitution, arises from penumbras of specific guarantees in the Bill of Rights, specifically the first, third, fourth, fifth and ninth amendments. *Griswald* v. *Connecticut,* 381 U.S. 479, 484-485, 85 S. Ct. 1678, 14 L. Ed. 2d 510 (1965). The constitutional right to privacy has been extended to include the right of the individual to be free from unwarranted governmental intrusion into matters affecting a person's fundamental rights. *Eisenstadt* v. *Baird,* 405 U.S. 438, 453, 92 S. Ct. 1029, 31 L. Ed. 2d 349 (1972). It encompasses the right of a patient to be free from unwanted infringements of bodily integrity, including medical treatment, in appropriate circumstances. *Superintendent of Belchertown State School* v. *Saikewicz,* 373 Mass. 728, 370 N.E. 2d 417, 424 (1977); *Matter of Quinlan,* 70 N.J. 10, 355 A.2d 647, 663 cert. den. *sub nom. Garger* v. *New Jersey,* 429 U.S. 922, 97 S. Ct. 319, 50 L. Ed. 2d 289 (1976).

Apart from constitutional considerations, the individual right to self-determination has long been recognized at common law. In *Union Pacific Ry. Co.* v. *Botsford,* 141 U.S. 250, 251, 11 S. Ct. 1000, 35 L. Ed. 734 (1891), the Court stated that "[n]o legal right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." The right of one's person is a right of complete immunity to be let alone. 141 U.S. at 251-2. This right includes the right of a competent adult to refuse life-sustaining medical treatment. *Application of Eichner, 102 Misc. 2d 184, 423 N.Y.S. 2d*

580, 593 (1979 affd. sub nom., Eichner v. *Dillon,* 73 A.D. 2d 431, 426 N.Y.S. 2d 517 (1980) aff'd., 52 N.Y. 2d 363, 438 N.Y.S. 2d cert. den. 454 U.S. 858 (1981); *Matter of Quackenbush,* 156 N.J. Super. 282, 383 A.2d 785 (1978); *Erickson* v. *Dilgard,* 44 Misc. 2d 27, 252 N.Y.S. 2d 705, 706 (1962).

Ordinarily a person may assert only his own constitutional rights. *Bell* v. *Planning and Zoning Commission,* 174 Conn. 493, 499 (1978). The courts have recognized the right of a guardian of the person to vicariously assert the right of an incompetent or unconscious ward to accept or deny medical care. *Matter of Spring,* 405 N.E. 2d 115, 119 (Mass. 1980); *Severns v. Wilmington Medical Center, Inc.,* 421 A.2d 1334, 1347 (Del. 1980); *Leach* v. *Akron General Medical Center,* 68 Ohio Misc. 1, 426 N.E. 2d 809 (1980); *Matter of Quinlan,* 70 N.J. at 41-42. To deny the exercise because the patient is unconscious or incompetent would be to deny the right. *Severns,* 421 A.2d at 1347. It is incumbent upon the State to afford an incompetent the same panoply of rights and choices it recognizes in competent persons. *Saikewicz,* 370 N.E. 2d at 426. In the instant case the Court finds that Kenneth Foody has standing to maintain this action as conservator of the person of Sandra Foody.

II

Countervailing State Interests

The right of an individual to refuse medical treatment is subject to being overridden by State interests in appropriate circumstances. *Id.* at 425; *Application of Eichner,* 423 N.Y.S. 2d at 593. Countervailing State interests include the preservation of life, the protection of the interests of innocent third persons, the prevention of suicide, and maintenance of the ethical integrity of the medical profession. *Leach,* 426 N.E. 2d at 814; *Saikewicz,* 370 N.E. 2d at 425.

The State has a legitimate interest in the preservation of human life. *Id.* This interest has justified court ordered medical intervention where routine medical treatment would likely allow an otherwise dying patient to lead a relatively normal, healthy life. *Commissioner of Correction* v. *Myers,* 379 Mass. 255, 399 N.E. 2d 452 (1979) (dialysis); *Application of President and Directors of Georgetown College, Inc.,* 118 U.S. App. D.C. 80, 331 F.2d 1000, *rehearing en banc den.* 331 F. 2d 1010, *cert. den.* 377 U.S. 978 (1964) (blood transfusion); *John F. Kennedy Mem. Hosp. v. Heston,* 58 N.J. 576, 279 A. 2d 670 (1971) (id.). The State's interest in preserving life weakens and the individual's right of privacy grows as the degree of bodily invasion necessary for treatment increases and the prognosis dims. *Matter of Quackenbush,* 383 A. 2d at 789. As the *Saikewicz* court aptly noted, the interest of the State in prolonging a life must be reconciled with the interest of an individual in rejecting the traumatic cost of that prolongation. 370 N.E. 2d at 425. "There is a substantial distinction in the State's insistence that human life be saved where the affliction is curable, as opposed to the State interest, where, as here, the issue is not whether but when, for how long, and at what cost to the individual that life may be briefly extended." *Id.* at 425-426.

The decisions generally frame the State's interest as being determined by the patient's prognosis, while the nature of the treatment defines the patient's interest. *See Matter of Conroy,* 190 N.J. Super. 453, 464 A.2d 303 (App. Div. 1983). In determining the patient's interest, not only should the nature of the treatment be considered, but the usefulness or benefits of the treatment as well. Whether serious burdens of treatment are worth enduring should depend upon how long the treatment will extend life and under what conditions.

In the present case, Sandra Foody's prognosis is extremely poor; she is never expected to resume cognitive, sapient life, and her physical condition, due to multiple sclerosis, continues to deteriorate. The degree of bodily invasion is great; she requires around the clock nursing care, drugs to control brain seizures, the assistance of a respirator, a lung cleaning suction catheter and a nasogastric feeding tube. To recognize the patient's right to decide to terminate an artificial life-sustaining treatment in these narrow and extreme circumstances would not undermine the State's interest in the preservation of life.

The next State interest requiring discussion is that of the maintenance of the ethical integrity of the medical profession. The decision whether to discontinue life-sustaining measures has traditionally been expressed by the distinction between ordinary and extraordinary treatment. *Matter of Conrov,* 464 A. 2d at 312. Under the distinction, ordinary care is obligatory for the patient to accept and doctor to provide, extraordinary care is optional. *Commission Report,* p. 82 *citing* McCartney, *Note,* 47 Linacre Q. 215 (1980). The standard definition of the terms is as follows. "Ordinary means are all medicines, treatments and operations which offer a reasonable hope of benefit and which can be obtained and used without excessive expense, pain, or other inconvenience. Extraordinary means are all medicines, treatments and operations which cannot be obtained or used without excessive expense, pain or other inconvenience, or if used, would not offer a reasonable hope of benefit." Kelly, *Medico-Moral Problems,* 129 (1959).

It is clear from the testimony that when Sandra Foody was brought into the emergency room, the use of a respirator was ethically required. She was in a state of respiratory attack, physically unable to consent to the treatment, her legal conservator had not yet arrived on the scene, and time was of the essence. The physicians' primary concern was to stabilize the patient's condition. At the time she came in, the physicians could not rule out improvement in her condition.

The issue which must be resolved is whether prevailing medical ethics require the continuation of a life-sustaining measure in light of significant downgrading of a patient's prognosis from the time of initiation of the treatment. The medical profession has devised clinical criteria for the determination of "brain death." *See* Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, *A Definition of Irreversible Coma,* 205 J.A.M.A. 377 (1968). However, when permanently unconscious patients do not meet the stated criteria, difficult questions are raised about the type and extent of care that should be provided.

Viewing the obligation to provide treatment as based upon whether the treatment offers reasonable hope of benefit to the patient, withdrawal of treatment should be ethically permissible where it no longer offers hope of benefit to the patient. *Commission Report,* p. 74-77. The Commission warns that requiring a higher justification for stopping treatment than for startint it will have serious adverse consequences, among which is the possibility that potentially life saving treatment will not be started because of fear on the part of health care personnel that once started, it will be difficult to stop if it proves of little benefit, but great burden, to the patient. *Id.* at 75.

That a patient may choose to have treatment withdrawn is compatible with the ethical mores which allow a competent patient, or his family if he is incompetent, to consent to the entry of a "DNR" (do not resuscitate) order on a patient's chart. The DNR order is based upon the philosophy that a person capable of giving informed consent has the right to make her own decision regarding medical care. *Id.* p. 240; *See Guidelines for Discontinuance of Cardiopulmonary Life-Support Systems under Specified Circumstances,* adopted by the L.A. County Medical and Bar Association, reprinted in *Commission Report,* p. 461-462.

In the present case, Sandra Foody's attending physician considers the use of the respirator an extraordinary measure, and notes that even with its use, the quality of her life is very poor. Consulting physicians are unable to recommend any diagnostic or therapeutic treatments which might improve her condition. Prevailing medical ethical practice does not, without exception, demand that all efforts toward life prolongation be made in all circumstances. Rather, as the courts in *Quinlan* and *Saikewicz* indicate, prevailing ethical practice seems to recognize that the dying are more in need of comfort than treatment. The right to refuse treatment in appropriate circumstances is consistent with existing medical mores. The Court finds that the present case presents appropriate circumstances for the exercise of that right.

The State interest in preventing suicide requires little discussion. An individual's determination to cease medical treatment pursuant to their right of privacy does not constitute suicide. *Matter of Quinlan,* 355 A. 2d at 670. This is so, because (1) in refusing treatment the patient may not have the specific intent to die and (2) even if he did, to the extent that death resulted from natural causes, the patient did not set the death producing agent in motion with intent to cause his own death. *Saikewicz,* 370 N.E. at 426, n. 11.

The final State interest which must be considered is that of protecting innocent third persons. In the present case, Sandra Foody has no children who might suffer emotionally or materially from the decision to withdraw life-sustaining systems. Nor, therefore, does the State have a *parens patriae* interest toward any potential wards. The Court finds that the interest of third parties in this case is either minimal or nonexistent and must be outweighed by the incompetent's right in question.

On the basis of the above analysis, the Court concludes that no State interest exists to the degree necessary to outweigh the right of Sandra Foody to exercise her right to refuse further life-sustaining treatment.

III

Exercise of the Right

Having ascertained the existence of a right on the part of the semi-comatose Sandra Foody to refuse further life-sustaining measures, the question is how that right may best be exercised. The *Quinlan* court noted that "[c]ourts in the exercise of their *parens patriae* responsibility to protect those under disability have sometimes implemented medical decisions and authorized their carrying out under the doctrine of 'substituted judgment.' *Hart* v. *Brown,* 29 Conn. Sup. 368 . . . (Super. Ct. 1972)." The *Quinlan* court authorized "the guardian and family of Karen [Quinlan] to render their best judgment, subject to [consultation with attending physicians and ethics committee], as to whether she would exercise [the right] in these circumstances." 355 A. 2d at 664. The rationale for this authorization was that an overwhelming majority of society would, "in similar circumstances, exercise such a choice in the same way for themselves or those closest to them." *Id.* The Massachusetts courts have adopted a similar standard. *Saikewicz,* 370 N.E. 2d at 430-431; *Matter of Spring,* 405 N.E. 2d at 122. The primary test in the substituted judgment standard is subjective, i.e., to determine with as much accuracy as possible the wants and needs of the incompetent individual, not necessarily what may conform to what the majority deem wise or prudent. *Saikewicz,* 370 N.E. 2d at 430. An expression of intent while competent is not essential, the opinion may be based upon knowledge of the individual gleaned from a family relationship. *Id.; Matter of Spring,* 405 N.E. 2d at 122. The decision should be "that which would be made by the incompetent person, if that person were competent, but taking into account the present and future incompetency of the individual as one of the factors which would necessarily enter into the decision making process of the competent person." *Saikewicz,* 370 N.E. 2d at 431.

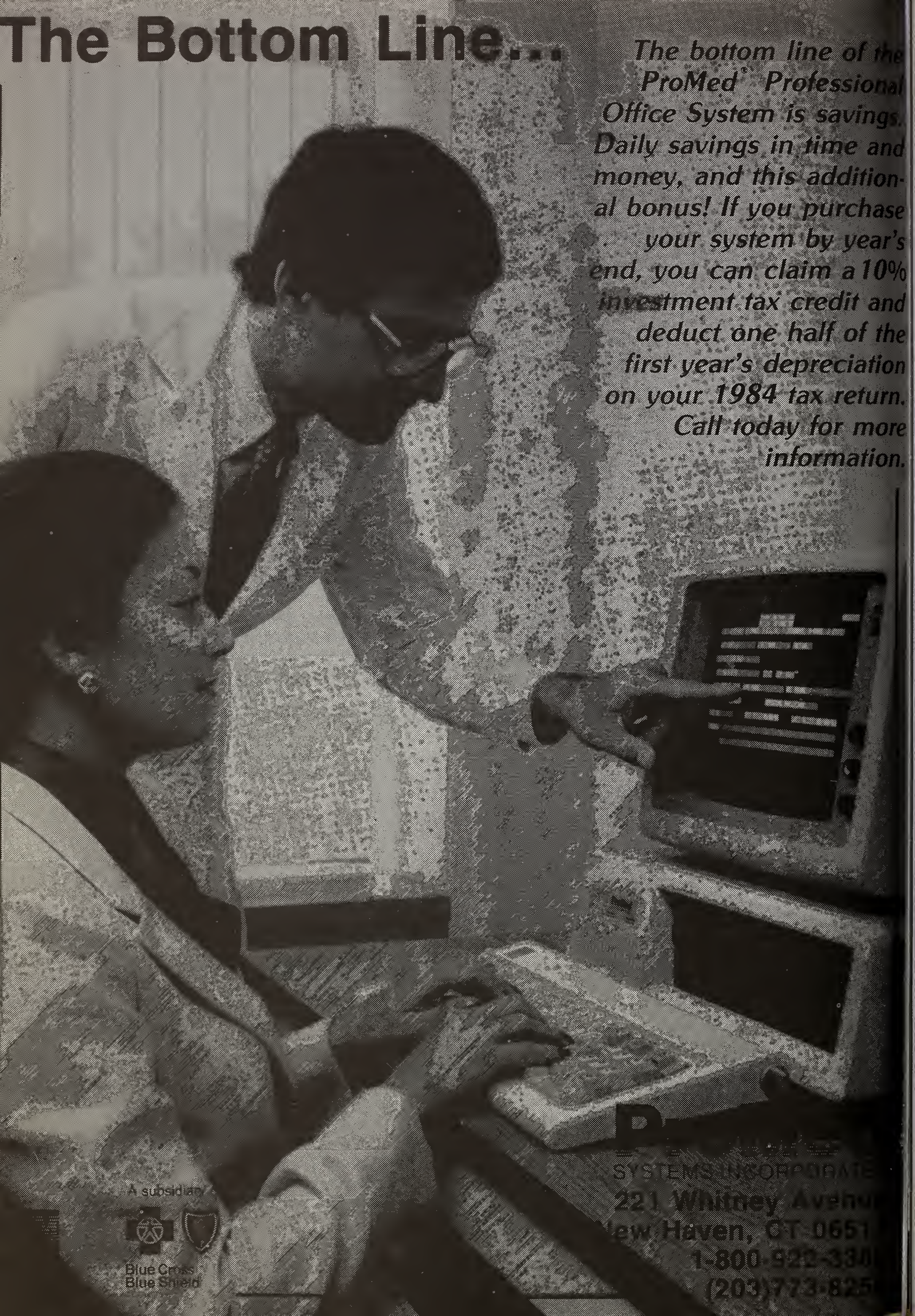
The analyses of the *Saikewicz* and *Quinlan* courts have been criticized for basing their decisions on what a majority would do in similar circumstances where there was in fact no evidence as to what the individual's choice would be. *Application of Eichner,* 423 N.Y.S. 2d at 596-597. The *Eichner* court believed that the result of both decisions was to permit a choice to be made for one person by another, not necessarily reflecting what the decision of the incompetent would have been. *Id.* On review, the Appellate Division of the New York Supreme Court adopted the substituted judgment test where a patient has not made his views known while competent. *Eichner* v. *Dillon,* 426 N.Y.S. 2d at 548.

If the exercise of the right is to be maintained where no expression has been made by an incompetent patient as to treatment, it must take place within the context of an analysis which seeks to implement what is in that person's best interests by reference to objective societally shared criteria. *See Commission Report,* p. 134-135. "In assessing whether a procedure or course of treatment would be in a patient's best interests, the decision maker must take into account such factors as the relief of suffering, the preservation or restoration of functioning, and the quality as well as extent of life sustained." *Commission Report,* p. 135.

Although Sandra Foody never expressed her view on whether she would want to be kept alive under the present circumstances, the evidence depicts her as an individual who was resigned to the acceptance of her affliction with multiple sclerosis and its inevitable consequences. Those consequences, i.e., debilitation and eventual death, do not appear to include life on the respirator on which she now depends. The treatment involved while unquestionably extending her life, offers no hope for the future. In the words of the attending physician, Sandra Foody can in no way interact with her environment. Where (1) the incapable patient's condition is permanent and irreversible and there is no reasonable medical probability that the patient ever will return to a cognitive state, (2) the patient's attending physician together with at least two other consulting physicians unanimously concur as to the patient's condition, and (3) there are concerned family members who in good faith wish to exercise through substitute decision making the patient's right to discontinue artifical life-support systems, it is our conclusion that the family lawfully may act as the patient's substitute decision maker and may decide to discontinue the use of the respirator and we so hold.

The defendants Manchester Memorial Hospital, its Executive Director, and the attending physician having stated they would comply with the court's ruling, plaintiffs do not press their request for injunctive relief. The Court finds, however, that the plaintiffs have carried their burden for permanent injunctive relief in the instant case and would be prepared to act on that request if the need arises.

Accordingly, it is this court's ruling that Sandra Foody's family, Kenneth and Ann Foody, may act as Sandra's substitute decision maker, and may decide to discontinue the use of all artificial devices calculated or intended to continue Sandra's respiration and pulse. If the decision is made to discontinue the use of all such devices and as a result death should occur, hospital personnel and attending physicians shall not be subject to criminal or civil liability because of such discontinuance.



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The Legal Status of the Medical Staff

JOHN HORTY, LL.B.

It's time that the hospital industry rid itself of the notion that the hospital medical staff is something separate from the hospital itself. It simply isn't. This idea is not only incorrect—it is legally dangerous.

If allowed to continue, more than a few hospitals will be forced to close their doors forever because of it. And physicians who may have thought that an "independent" medical staff was in their best interest will find themselves facing multimillion dollar antitrust and negligence suits as a result.

The application of the antitrust laws to hospitals and physicians has made the difference. The medical staff of the hospital today is no more separate than the nursing department. And the hospital is just as answerable for what it does and what it does not do.

The simple and undeniable fact is that the hospital medical staff is an integral part of the hospital itself. Otherwise, both the hospital and physicians who practice there will be courting legal and financial disaster.

Action-Kit has made these points time and again. But the legal and fiscal climate facing hospitals today is so volatile that we feel compelled to devote an entire issue to this most important proposition: unless the hospital and its medical staff operate as a single entity neither will survive into the 1990s. The following article will point out why this is so, both from a legal and operational standpoint.

How the Law Views Hospitals and Medical Staffs

The best starting point is the description of the modern hospital given as part of the United States Supreme Court's decision in *Abbott Laboratories v. Portland Retail Druggists Association, Inc.*, 425 U.S. 1 (1976).

That case dealt with the question of whether a hospital could purchase drugs from a supplier at a lower rate than that given to retail sellers, and then resell the drugs to patients, employees and staff physicians. The drugstore owners who challenged this practice claimed it would be in violation of the Robinson-Patman Act, a federal antitrust statute prohibiting sellers from granting price preferences to large buyers that are not granted to smaller customers. In discussing the applicability of the Nonprofit Institutions Act, passed two years after Robinson-Patman to allow suppliers to grant price favors to charitable institutions such as hospitals and schools, the court observed:

"Some hospitals, indeed, truly have become centers for the 'delivery' of health care. The nonprofit hospital no longer is a receiving facility only for the bedridden, the surgical patient, and the critical emergency. It has become a place where the community is readily inclined to turn, and—because of increasing costs, physician specialization, shortage of general practitioners, and other factors—is often compelled to turn, whenever a medical problem of import presents itself. The emergency room has become a facility for all who need it and it no longer is restricted to cases previously authorized by members of the staff. And patients that not long ago required bed care are often now treated on an ambulatory and outpatient basis."

The idea that a modern hospital could be held responsible for the quality of medical care given to a patient is not so new. In *Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957) the New York Court of Appeals said:

"The conception that the hospital does not undertake to treat the patient, does not undertake to act through its doctors and nurses, but undertakes instead simply to procure them to act upon their own responsibility, no longer reflects the fact. Present-day hospitals, as their manner of operation plainly demonstrates, do far more than furnish facilities for treatment. They regularly employ on a salary basis a large staff of physicians, nurses and interns, as well as administrative and manual workers, and they charge patients for medical care and treatment, collecting for such services, if necessary, by legal action. Certainly, the person who avails himself of 'hospital facilities' expects that the hospital will attempt to cure him, not that its nurses or other employees will act on their own responsibility."

Likewise in the famous case of *Darling v. Charleston*

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Community Memorial Hospital, 211 N.E.2d 253 (Ill. 1965), where negligent treatment in the emergency room by a staff physician caused the young patient to lose his leg, the Illinois Supreme Court concluded that it was "both desirable and feasible that a hospital assume certain responsibilities for the care of the patient." The holding in *Darling,* that a hospital can be held liable for the negligent acts of its staff physicians, has been echoed by courts in other states time and time again since the original opinion was handed down.

Hospitals are like all other corporations. The ultimate responsibility for the corporation's conduct rests with the corporation's governing board. By virtue of state corporate law (or special statutes in the case of many public hospitals), as well as the articles of incorporation and bylaws of each individual hospital, the hospital's board is charged with the overall authority for the conduct of the hospital.

This authority, and the responsibility that goes with it, has been recognized by virtually every court faced with the issue. It has been recognized as well by various accreditation and regulatory bodies that deal with hospitals, including the Joint Commission on Accreditation of Hospitals, the American Osteopathic Association, the federal Medicare program and state licensing agencies.

As the *Darling* case and those many cases that came after it illustrate, the courts have extended the legal responsibility of the governing board in areas that in the 1930s were thought of as being within the sole province of physicians—namely, the quality of medical care delivered in the hospital. This general responsibility of the board in no way relieves each individual physician of personal responsibility and liability for the care he delivers. It does mean, however, that the board will be held accountable if it fails to provide mechanisms by which deficiencies or potential problems with respect to medical care by physicians can be identified and dealt with before they result in harm to a patient. This duty includes the granting of medical staff appointment and privileges, and the establishment of a competent medical staff.

In *Moore v. Borad of Trustees of Carson-Tahoe Hospital,* 495 P.2d 605 (Nev. 1972), the Supreme Court of Nevada recognized that this special duty of the governing board meant that the board had the right to terminate the medical staff appointment and clinical privileges of a physician, even in a public hospital. The court's observations are key to an understanding of the relationship between hospital and physician:

"Today, in response to demands of the public, the hospital is becoming a community health center. The purpose of the community hospital is to provide patient care of the highest possible quality. To implement this duty of providing competent medical care to the patients, it is the responsibility of the institution to create a workable system whereby the medical staff of the hospital continually reviews and evaluates the quality of care being rendered within the institution. The staff must be organized with a proper structure to carry out the role delegated to it by the governing body.

"All powers of the medical staff flow from the board of trustees, and the staff must be held accountable for its control of quality." (Emphasis added.)

"The right to enjoy medical staff privileges in a community hospital is not an absolute right, but rather is subject to the reasonable rules and regulations of the hospital. Licensing, per se, furnishes no continuing control with respect to a physician's professional competence and therefore does not assure the public of quality patient care. The protection of the public must come from some other authority, and that in this case is the Hospital Board of Trustees."

The only means by which the governing board can assure itself that quality medical care is provided to its patients is to establish mechanisms by which applicants to the medical staff are adequately credentialled and current appointees are adequately monitored.

Perhaps the most comprehensive discussion of this duty can be found in the Wisconsin case of *Johnson v. Misericordia Community Hospital,* 294 N.W.2d 501 (Wis. App. 1980) *affd,* 201 N.W.2d 156 (Wis. 1981). The facts of this case were discussed in the October 1980 issue of *Action-Kit.* Basically, it involved a negligence case in which the plaintiff attempted to hold the defendant hospital independently liable for the malpractice of a physician on the hospital's medical staff on the ground that the hospital did not adequately credential the physician.

The court agreed with the plaintiff that the hospital had such a duty. The court stated:

"We are of the opinion that Misericordia's failure to adhere to established procedures with regard to the 'credentials process' involved a breach of the separate and distinct duty owed to potential patients and, therefore, created a foreseeable and unreasonable risk of harm to such patients."

In examining whether the hospital had a duty, the court examined the Wisconsin law. As the court said, the Wisconsin Administrative Code "makes it clear that the medical staff is 'responsible to the governing body of the hospital for the quality of all medical care provided patients in the hospital, and for the ethical and professional practices of its members.' (Citation omitted) The measure of quality and the degree of quality control exercised in a hospital, then, is the direct responsibility of the medical staff.

"Thus the medical staff emerges not as a separate entity but as part of the legally constituted hospital corporation, having been created by the governing board. The medical staff becomes an organized extension of the board, carrying out necessary quality control functions. (Emphasis added) The board in turn must inevitably render public accountability for the effective discharge of those functions. Achievement of the goal of good patient care is a direct result of an organization's effectiveness in identifying less-than-ideal patterns of practice in its potential staff. Without diligence in the areas of preventive and corrective measures by its governing members, a hospital could easily develop into an enclave of professional obsolescence and gross incompetence."

Aside from holding that hospitals can be held liable for failing to adequately credential physicians, the opinion in the *Johnson* case made a very important observation about the nature of the medical staff: that the medical staff is an integral part of the hospital corporation. This is the only correct way to view the medical staff. Any other view results in serious operational difficulties and dramatically increases the potential for hospital and physician liability.

The Dangers of an "Independent" Medical Staff

Hospital executives do not need to be persuaded that an "independent" medical staff, one accountable only to itself and not the hospital, would be an organizational and legal nightmare. The primary purpose of any hospital is the provision of medical services. The only persons within the hospital's organization who are capable of providing those services are the physicians on the hospital's medical staff. Thus, if the hospital is to survive as a viable institution, the medical staff must be fully integrated into the hospital's organizational structure. It makes no sense whatsoever for any business, especially one as large and complex as a modern hospital, to allow that portion of the business concerned with offering its primary product line to the public to act as an autonomous or quasi-autonomous unit.

Unfortunately, all too many hospitals allow their medical staffs to look and act like separate organizations. This kind of "organizational schizophrenia" can only hinder the hospital's ability to successfully compete in the marketplace. It will also result in legal pitfalls.

In the first place, if the medical staff is viewed or treated as a separate entity from the hospital, the physicians on the medical staff could be held responsible for insuring that all of their colleagues on the staff are competent to practice. Thus, if one physician on the staff were sued for malpractice, all of the rest could be held liable for his negligence on the theory that they should not have allowed him to practice on the staff.

Just such an argument was made in the case of *Corleto v. Shore Memorial Hospital,* 350 A.2d 534 (N.J. Super. 1975). There, a New Jersey trial court went so far as to hold that every physician on the medical staff of the defendant hospital could be named as individual defendants along with the hospital in a suit arising out of the alleged malpractice of one physician on the staff. The court based this ruling on its view that the medical staff was an "unincorporated association." Thus, all of its "members" could be held jointly responsible if one of them was negligent. The case was settled before trial, so there was never any finding concerning the actual liability of any of the parties.

The ruling that the staff was an unincorporated association was legally incorrect. The medical staff is part of the hospital. It has no existence apart from the hospital. Its membership and bylaws are subject to the approval of the hospital board. An unincorporated association, on the other hand, is an independent organization with complete control over its own bylaws, membership and affairs. If it becomes subject to the control of another organization, it ceases to exist. Therefore, a medical staff cannot legally be considered an unincorporated association.

Nevertheless, some medical staffs still function as if they were organizations separate and apart from their hospitals, in direct contradiction to these legal principles. Even where they do not, medical staff bylaws often contain language that leaves the mistaken impression that the staff is a distinct legal entity. Examples include references to the staff as an "organization," statements that the physicians practicing in the hospital have "organized themselves" into a medical staff and similar language that tends to portray the staff as the equivalent of a collective bargaining unit as opposed to an operational extension of the board.

This kind of language can be used against the physicians and the hospital as the *Corleto* case demonstrates. Since *Corleto,* more and more plaintiff's attorneys have begun to name all the physicians on a given medical staff as defendants in malpractice suits. This is done not so much in the hope of finding them all liable, but rather as a tactic to intimidate one or more of the named defendants into providing evidence against the physician who is the main target in return for being dropped from the suit.

Certainly, if the staff is viewed as independent of the hospital by courts at least each and every officer, department chairman and committee member is risking personal liability. And, if they are acting for the medical staff and not the hospital—and the court so finds—the hospital's insurance will not cover them. For such insurance only covers actions done for the hospital.

While nothing can prevent a plaintiff from attempting this gambit, it is far less likely to succeed if the medical staff clearly acts as an integral part of the hospital. If it is, the other physicians on the staff can be more easily stricken as defendants during the preliminary stages of the case, since it will be clear that the hospital's board is responsible for the actions of the physicians on its staff, not the physicians themselves. However, where the medical staff "appears" to be something separate from the hospital, a court may be less likely to summarily dismiss the suit against all of the staff's appointees.

Antitrust Liability

A medical staff that appears to be separate from the hospital also increases the potential for antitrust liability on the part of the hospital, of the medical staff and of the individual physicians on the medical staff. Dramatic evidence of this was provided by the case of *Weiss v. York Hospital,* 548 F. Supp. 1048 (M.D. Pa. 1982).

In that case, an osteopath who was denied medical staff appointment and clinical privileges at York Hospital sued the hospital and its medical staff as a separate entity. He also sued nine individual physicians. His complaint alleged that the hospital and its staff, as well as various physicians on the staff, had conspired to deny him the clinical privileges he requested in violation of federal antitrust laws. After a lengthy trial, both the judge and jury hearing the case found that the hospital had conspired with its medical staff to deny the plaintiff access to the hospital's facilities.

Given the proper view of the hospital medical staff, such a finding would be impossible. The medical staff is part of the hospital and it is a fundamental premise of antitrust law that a single corporation cannot conspire with itself. Therefore, there can be no "conspiracy" between the hospital and its staff to deny any practitioner the right to practice there.

Decisions on whether to grant or deny staff privileges and appointment must only be made by the hospital's board. Hospital licensing regulations in virtually every state, as well as accreditation standards established by the Joint Commission on Accreditation of Hospitals and the American Osteopathic Association make it very clear that the hospital board must exercise final responsibility with respect to appointment, reappointment and clinical privileges of the physicians on its medical staff. Physicians on the medical staff act in these decisions with their technical evaluation of clinical competence (credentialling) and their *recommendation,* but it is the governing board that *decides.*

In addition, those same regulations and accreditation standards make it very clear that the board is responsible for the quality of care rendered in the hospital by individuals appointed to the medical staff. While the board delegates responsibility to officers, departments and committees of the medical staff for the monitoring and review of those activities, the final responsibility must rest with the board.

Hospitals should therefore be organized and operated so that these legal duties can be fulfilled. Since the board is responsible for the exercise of these functions and for the quality of care rendered in the hospital, any and all parts of the hospital corporation are directly responsible to the board, including the medical staff. The board cannot exercise its authority over an entity that is separate from the hospital corporation. This delegation of authority to the medical staff is *no* different than the board's delegation of certain of its legal functions to hospital management, nursing, housekeeping, security, laboratory and other functions of the hospital operation.

However, where the staff gives the appearance as being something separate from the hospital, results such as those in *Weiss* and *Corleto* will become all the more likely—even though they are legally incorrect in our judgment. The current legal climate with respect to the health care field is volatile enough without adding to the potential for hospital and physician liability in this regard.

The recent changes in Medicare reimbursement resulting in a prospective payment system based on diagnostic related groups make it all the more imperative for the hospital and its medical staff to operate as one. Due to the nature of this new reimbursement scheme, the hospital's continued financial viability is now inextricably intertwined with the economic way in which physicians on its medical staff practice medicine. The hospital now can be significantly adversely affected in its finances by the clinical decisions of its physicians. The board will have to take whatever action is necessary to preserve the hospital's fiscal viability. It is no longer acceptable for the board to ignore the economic practices of appointees to the medical staff.

Some Practical Suggestions

While the true test of whether a hospital medical staff is an integral part of the hospital hinges on how the board, management and staff state and actually carry out their duties, there are a few things that can be done organizationally to make certain the staff and hospital appear to any court as one. These include the following:

- The hospital's corporate bylaws should specifically set forth the board's authority with respect to the medical staff. It should be made clear that the powers of the staff officers, committees and department heads flow from the board. It should also be stated that the medical staff bylaws, rules and regulations are subject to board approval and may be amended by the board with or without staff approval.

  The medical staff bylaws, in turn, should state at the outset that the staff is an integral part of the hospital corporation. They should not include any preamble or purpose clauses, which only make sense if the staff is a separate entity on the staff. The term "staff appointee" rather than "member" more accurately reflects the physician's relationship to the hospital and does not lend itself to the incorrect conclusions that the staff is a "membership organization" or unincorporated association.

- Cooperative ventures between hospitals and physicians—especially PPOs—should be structured so the hospital is contracting with individual physicians, not the medical staff as a group. Some PPO models where most of the physicians on the staff are involved encourage the staff to separately incorporate or even "unionize" in order to jointly offer services with the hospital. This is at once unnecessary and unwise. If the staff holds itself out to the public as a separate entity for one purpose, it will likely be treated as such for other purposes as well—with the kind of unfortunate results as occurred in *Corleto* and *Weiss.*

- All decisions with respect to individual staff appointments and clinical privileges must be ultimately made by the board. While this should be obvious, the process by which recommendations on the same are sent to the board are just as important. **Under no circumstances should such recommendations be made by the entire staff.** Aside from adding to the impression that the staff is an entity unto itself, allowing the whole staff to have a say in whether a given physician can practice at the hospital raises serious antitrust concerns as well. Recommendations of this kind should only be made by duly authorized committees of the staff.
- Medical staff dues, if required at all, should be paid directly to the hospital, and the approval of hospital management should be required prior to any disbursement of those funds. All too often, medical staff dues are paid unthinkingly year after year into accounts that are not subject to hospital ownership and control. They thus provide yet another reason for malpractice plaintiffs to name the entire staff as defendants, especially if they are large and inviting sources of funds for a potential settlement separate from the hospital.
- Finally, hospital approval should be required before any consultants are retained to assist with medical staff functions. This is especially true with respect to attorneys. Allowing the medical staff to be advised by its own "consultants" paid by it is an invitation to disaster. Since the medical staff is part of the hospital, its interests cannot be represented separately from the hospital because its interests are the hospital's, and vice versa. Of course a group of physicians can hire an attorney or anyone else to assist them. The medical staff cannot, any more than any other part of the hospital. Perhaps the most damaging piece of evidence in the allegation of antitrust conspiracy between medical staff and hospital is that the medical staff had its own attorney **representing** its own interests.

The legal status of the medical staff has changed as the hospital has changed legally. When, as in the past, the hospital was seen simply as a **place** where physicians plied their trade and took their patients, the notion of the medical staff as separate from the hospital was a traditional view. Today, as the courts have said, the hospital is a **thing,** a dynamic institution with responsibilities to its patients and the community at large. Insofar as the courts, federal and state regulatory agencies and accreditation bodies are concerned, there can be only one conclusion. The medical staff is part of the hospital. Fortunately, this fact best protects hospital and individual physicians from antitrust and negligence liability.

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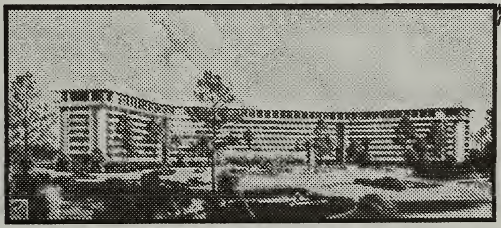

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The Legal Status of the Medical Staff

DAVID E. WILLETT, J.D.

Introduction

In this new era of cost containment, competition, and commercialization, the relationship between the hospital governing board and the medical staff is more important than ever. It is time to confront a threat to existing, effective relationships.

For several years now, a few hospital attorneys have been preaching a new gospel. They argue that the medical staff is simply an "organizational extension" of the board, like any hospital department. They particularly assert that there is no such thing as a "separate" or "self-governing" medical staff, insofar as the law is concerned.

The most prominent advocates of this position are John Horty and Eric Springer, partners in a Pittsburgh law firm. Horty and Springer are personable, articulate lawyers wholly dedicated to their hospital clients. They have a national audience, through their frequent participation in Estes Park Institutes and regular publication of their "Action Kit for Hospital Law." At a recent Estes Park conference, and in the January "Action Kit" publication, Horty and Springer have once again presented their views.

We are compelled to challenge their assertions, for several reasons. First of all, the cases they cited as authority do not support their arguments. Secondly, we think the advice they offer isn't good, from the standpoint of either board or staff. It invites the board to accept responsibilities which the law has not imposed, and which the board or administration is ill prepared to discharge. In terms of working relationships, this advice invites confrontation, to the detriment of all concerned. Finally, this approach would remove a check and a balance which serves a vital public purpose, particularly in this time of change.

Some hospital administrators and some hospital trustees may be entranced by the notion that the medical staff is no different than the dietary department. More thoughtful individuals may be less comfortable with the obvious implication, which is that administrators or trustees should have the same responsibility for medical services as they do for the food service. Horty and Springer would argue that the courts have already imposed such a responsibility. When we look at the cases we find this isn't true. We come to the same conclusion when we examine other legal bogeymen they raise.

What does "separate" mean?

Horty and Springer seem to argue that because the medical staff is to be found within the hospital's corporate structure, it can have no separate existence, responsibilities or—most of all—rights. They conclude that ultimate responsibilities assigned to a corporate board exclude the existence of other entities within the same structure, for any purpose whatsoever. The law takes a different approach. "Separateness" depends very much on the issue at hand.

In *American Mutual Liability Ins. Co. v. Superior Court* (1974) 38 Cal.App.3d 579, 592, the court described an entity comprised of numerous parties in language which might be equally applicable to the hospital-medical staff relationship.

> This entity may be conceived as comprising a unitary whole with intramural relationships and reciprocal obligations and duties each to the other quite separate and apart from the extramural relations with third parties or with the world at large.

The court's characterization of this relationship simply reflects reality: a whole can have many parts. Numerous cases recognize legal "separateness" of a part within a whole, in a variety of situations, even though the component in question is subject to varying degrees of control by the parent or composite body. Both California and federal courts have recognized the separate legal status of unincorporated associations subject to at least the measure of control exercised by a hospital's governing body over the medical staff. See, e.g., *Killeen v. Hotel*

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and Restaurant Employees Etc. League (1948) 84 Cal.App.2d 87 (recognizing independent legal existence of local union even though it was bound by bylaws and constitution of parent association); *Associated Students of University of California at Riverside v. Kleindist.* (C.D. Cal. 1973) 60 F.R.D. 65 (student organization is not a mere sub-unit of the Regents of the University of California). All that is required under California law for a determination of separate legal status is "(1) a group whose members share a common purpose, and (2) who function under a common name under circumstances where fairness requires the group be recognized as a legal entity." *Barr v. United Methodist Church* (1979) 90 Cal.App.3d 259; Corporations Code §§24000; 20001; 21000. Indeed, the California Supreme Court has expressly referred to the medical staff as "an unincorporated association organized under the auspices of the hospital's board of directors." *Anton v. San Antonio Community Hospital* (1977) 19 Cal.3d 802, 809. There is simply no support for the contention that the law precludes recognition of the medical staff as a separate entity.

How the law will view the relationship between hospitals and medical staffs will depend entirely upon the matter at issue. The "Action Kit" article cites *Abbott Laboratories v. Portland Retail Druggists Assn., Inc.* (1976) 425 U.S. 1, as describing the legal relationship between staff and hospital. The case really doesn't deal with this relationship. The court's task was to determine whether the Nonprofit Institutions Act exempted nonprofit hospitals from the price discrimination proscriptions of the Robinson-Patman Act. Describing the role of hospitals in the community, the court used broad language which insured that hospitals receive the benefit of the exemption, but that language had nothing to do with medical staff-hospital relations. Indeed, it appears that the court recognizes the distinction between the hospital and medical staff, particularly where the court says:

> The physician staff member, though not an employee in the technical sense of being full time in the hospital's service and on its payroll, nevertheless is vital to its existence. *It is he who* supplies the patient and who *engages,* perhaps directly and *at least to some extent through the staff organization,* in the formulation of the hospital's professional and operative policies.

What about "corporate liability?"

In challenging the concept of a separate staff, these advocates frequently cite personal injury cases, asserting that "corporate liability" imposed in these cases demands an end to separate existence for the medical staff. However, the argument falls apart when we examine the cases. For instance, *Bing v. Thunig* (N.Y.App. 1957) 143 N.E.2d 3, examined the hospital's liability for the negligence of its *employees* involved in medical rather than administrative tasks. This case is not even a socalled "corporate liability" case, and in no way supports the premise that ignoring the medical staff affects liability.

Horty and Springer invariably invoke two cases, *Darling v. Charleston Community Memorial Hospital,* and *Johnson v. Misericordia Community Hospital,* as foundation stones for their contention that the hospital has such responsibility for acts of staff physicians that the self-governing medical staff must be abandoned. Their reference to the medical staff as "an organized extension of the board" is indeed a misquote taken from one of the decisions in the *Johnson* case. However, the *Johnson* opinion they quote is not the final decision by the Wisconsin Supreme Court, 301 N.W.2d 156 (1982) but an intermediate appellate decision 294 N.W.2d 501 (1980). If they were consistent, these advocates should also recognize the intermediate appellate court decision in the *Darling* case. Neither appellate decision reflects the law of the case, established in superseding state Supreme Court opinions, but the *Darling* appellate court decision does contain the facts which the Illinois Supreme Court considered in reaching the ultimate decision, found at 211 N.E.2d 253 (1965).

Dissecting the Darling decision

In *Darling,* the appellate court decision, 200 N.E.2d 149, sets out the facts in excruciating detail. "Pat" Darling broke his right leg in a college football game. He was brought to the Charleston Hospital emergency room. In this forty-six bed hospital, there was no designated surgical staff. Two orthopedic surgeons were on the "consulting staff." Dr. Alexander, a general practitioner, was called to the ER, and placed a cast on the leg. Darling was in the hospital for 14 days. During that period, the hospital chart and the testimony of witnesses establish unrelenting pain in the fractured limb, lack of feeling in the toes, and a foul odor. Both the appellate court and the Supreme Court decision make it clear that the damages awarded Darling for the eventual loss of his leg were supportable on the basis that the nurses were negligent, failing to test for circulation or recognizing "conditions that signal a dangerous impairment of circulation in the plaintiff's leg." The Supreme Court decision also says that second ground for hospital liability might be " . . . that the hospital failed to review Dr. Alexander's work or require a consultation; the only issue is whether its failure to do so was negligence. On the evidence before it, the jury could reasonably have found that it was."

Reading the appellate court decision, we find that the evidence before the jury was that Dr. Alexander had been in practice for more than 30 years. Although he testified that he had set between 200 and 300 legs during this period of practice, the plaintiff presented evidence that the only fracture cases he had set personally in the three years preceding (sic) plaintiff's hospitalization were two ankle injuries, and one of these resulted in a nonunion. From the testimony, the jury could have concluded that Dr. Alexander had little knowledge of orthopedic literature or standards of practice. There was extensive evidence as to JCAH and licensing requirements imposed upon a hospital, with respect to its medical staff. Reviewing the facts, the clearly identifiable theme of the plaintiff's case is not that the hospital should be liable because Dr. Alexander made a mistake, but rather that Dr. Alexander was not competent to provide the services which young Darling required, and that the hospital failed to do those things which a hospital ought to do. Had the hospital acted properly, it might have avoided Dr. Alexander's involvement beyond the limits of his competence. It certainly would have addressed his continued sole responsibility for the case, if hospital employees had properly realized the need for consultation or intervention by qualified personnel. The liability which was imposed on the hospital in *Darling* was for the hospital's *own negligence.* To say that *Darling* holds that a hospital can be held liable for the negligent acts of its staff physicians is misleading, because this assertion is at best a half-truth.

The real holding in Johnson

Horty and Springer are not the only hospital attorneys who misconstrue *Johnson v. Misericordia Community Hospital,* but their use of the appellate court decision, 294 N.W.2d 501 (1980), rather than the Supreme Court decision, 301 N.W.2d 156 (1981), is particularly interesting. In California, the intermediate appellate court decision becomes a nullity when the Supreme Court grants review, and use of the appellate court decision as authority is forbidden. Unlike California, Wisconsin publishes appellate court decisions even if they are later superseded by opinions of the Supreme Court, but, just as in California, it is the Supreme Court decision which is authoritative. In the *Johnson* case, the Supreme Court did not use the extreme language which the appellate court used, and did not say that the medical staff could not be separate or self-governing. The Supreme Court, unlike the appellate court, also chose to ignore an article by Mr. Horty on this subject. We can understand why the "Action Kit" authors prefer to cite the appellate court decision, but one must look to the Supreme Court decision for the law.

In *Johnson,* the Wisconsin Supreme Court opinion notes that " . . . the court record and the hospital records are devoid of any information concerning the procedure utilized by the Misericordia authorities in approving either (the surgeon's) appointment to the staff with orthopedic privileges, or his elevation to the position of chief of staff . . . Further (the medical staff coordinator) stated that an examination of the Misericordia records reflected that at no time was an investigation made by anyone of any of the statements recited in his application." Not surprisingly, the jury found that the hospital was negligent in granting orthopedic surgical privileges to a surgeon who had been in trouble at numerous other hospitals, saying that "the failure to investigate a medical staff applicant's qualifications or the privileges requested gives rise to a foreseeable risk of unreasonable harm and we hold that a hospital has a duty to exercise due care in the selection of its medical staff." This was held to be a "direct and independent responsibility to its patients." The court concludes:

> The final appointing authority resides in the hospital's governing body, although it must rely on the medical staff and in particular the credentials committee (or committee of the whole) to investigate and evaluate an applicant's qualifications for the requested privileges. However, this delegation of the responsibility to investigate and evaluate the professional confidence of applicants for clinical privileges does not relieve the governing body of its duty to appoint only qualified physicians and surgeons to its medical staff and periodically monitor and review their competence.

In *Johnson,* this state Supreme Court was confronted by a hospital denying the existence of any legal duty whatsoever, while conceding that it had done absolutely nothing to investigate the application of a discredited surgeon. It is therefore not surprising that the court found the hospital to have an independent duty. Though this is disquieting to hospital boards, it should be pointed out that *Johnson* was not a case where a conscientious board or administrator was unhorsed by medical staff dereliction. In fact, the clear inference in the *Johnson* decision is that there was no functioning medical staff at this hospital, and thus the case hardly stands for the proposition that the organized staff is threatening of itself.

Another case these authors cite, *Moore v. Board of Trustees of Carson-Tahoe Hospital* (Nev. 1972) 495 P.2d 605, was not a personal injury case, but involved the expulsion of a physician for specific misconduct, on the recommendation of the medical staff. Despite some generalized language regarding board responsibility and prerogatives, the relationship of the medical staff to the hospital was not in issue or discussed, and various broad statements by the court are specifically based on the statutory scheme applicable to public hospitals in Nevada.

What is "corporate liability?"

It is noteworthy that none of these "corporate liability" cases describe a situation where the exercise of self-governance lead to hospital liability. These are cases where the hospital failed to do its job. The argument that self-governance results in serious operational difficulties and dramatically increases the potential for hospital and physician liability is not supported by the reported cases, or by our own experience. In fact, it is our perception that hospital exposure to liability will be dramatically expanded if the hospital assumes the measure of responsibility which must accompany obliteration of the separate professional staff. The hospital can protect itself by insisting that the medical staff function as self-governing medical staffs are intended to function.

Indeed, it is possible that the elimination of the medical staff as a separate entity will *expand* the potential liability of hospitals in professional liability actions. Traditionally, hospitals had no liability for the negligence of members of the medical staff. See, e.g., *Mayers v. Litow* (1957) 154 Cal.App.2d 413, 417-418. Inroads on this principle have generally been based on the view that the function of hospitals, and the public's perception of the functions of hospitals, have expanded. See, e.g., *Elam v. College Park Hospital,* 132 Cal.App.3d 332, as modified, 133 Cal.App.3d 94a. However, most jurisdictions which have extended liability to the hospital for the negligence of medical staff members have limited that liability to situations in which the hospital was negligent in the initial selection or periodic evaluation of the competency of physicians on the staff. Cases imposing liability against the hospital under these circumstances have been predicated on the finding of breach of a separate duty, not on a theory of respondeat superior for the physician's negligence. Moreover, these cases have almost uniformly recognized the separate existence of the medical staff and the hospital's duty to defer to the medical staff in the first instance. See, e.g., *Johnson v. Misericordia Community Hospital,* 301 N.W.2d at 174 ("The final appointing authority resides in the governing body, although it must rely on the medical staff and in particular the credentials committee (or committee of the whole) to investigate and evaluate the applicant's privileges."); *Elam v. College Park Hospital,* 132 Cal.App.3d at 342 (same). These cases suggest that the hospital may be able to defend themselves successfully by showing that the hospital reasonably relied on the medical staff's recommendations. See 14 Pacific Law Journal at 823-825. Treating the medical staff like employees eliminates this defense.

The real threat of "self-governance"

For whatever reason, these authors see the self-governing medical staff as a threat, and cite various "dangers" so long as self-governing staffs are recognized. Illogically, they claim that the self-governing staff cannot be "accountable," or is accountable "only to itself." Obviously, proper bylaws provide not only "accountability" but also establish mechanisms for "accountability" which are likely to be workable. Lawyers may relish confrontation and the legal warfare predictable when unilateral edict governs "accountability," but this is not the premise of well-structured bylaws. Most contractual relationships provide for accountability between the parties, and the relationship between board and staff set out in the bylaws should be no different.

If this advice is really intended to advance a goal of maximized revenue and profits, one can more easily understand why self-governance is threatening. The medical staff's primary purpose is to ensure high quality care. In pure dollar terms, it may be possible to compete more successfully in the market place if quality is sacrificed. A staff which separately speaks for the patient is then a threat. That is a compelling reason for maintaining the integrity of the self-governing medical staff.

Is the separate staff dangerous to physicians?

The Action Kit article appears solicitious of physicians, telling them that physicians risk individual liability if medical staffs are self-governing. This intimidation is not supported by the cases. We are unaware of any case in which the members of a medical staff have been held personally liable for the failure of other members to perform medical staff functions adequately. *Corleto v. Shore Memorial Hospital* (N.J. Super. 1975), 350 A.2d 534, does not come close. At the very most, this is a *trial court* opinion which allowed the naming of a medical staff as an additional defendant in a professional liability suit, on the premise that it made no difference whether or not the staff was joined as a unincorporated association because "plaintiffs could have named all 141 doctors individually as defendants." *Corleto* does not begin to discuss what the plaintiff would have to prove to recover from the medical staff or from any of its members. It certainly is no authority for the proposition that members of the medical staff who have not themselves been negligent have any personal liability if the court allows suit against the staff, whether as a body or as a unincorporated association. Particularly in California, membership does not mean personal liability.

Most health lawyers agree that the *Corleto* court was wrong when it concluded that the medical staff could be sued by a patient for the negligent performance of peer review functions. As discussed in greater detail in "Hospital Corporate Negligence Comes to California: Questions in the Wake of *Elam v. College Park Hospital,*" 14 Pacific Law Journal 803 (1983), the medical staff's duty is to the governing body, not the public; the public perceives the hospital, not the medical staff as having responsibility, and the imposition of liability would contravene public policy by discouraging the staff from participating in peer review. This argument applies with even greater force to prohibit imposition of liability on individual members of quality assurance committees.

What happens if the staff is sued?

Even assuming the medical staff has a duty which runs to the public, physicians should carefully examine the contention that individual staff members face increased liability as a result of the medical staff's status as an independent entity. It does not appear that mere membership in an association creates personal liability for the association's obligations under California law, especially where the association, like most if not all medical staffs, is run on a nonprofit basis. A judgment against an unincorporated association may be enforced only against the property of the association. Corporations Code §24002. Moreover, even if a member is separately named and served, California courts have consistently held that members are not liable for the unlawful acts of other members "without their participation, knowledge or approval." *Orser v. George* (1967) 252 Cal.App.2d 660; *Marshall v. International Longshoremen's and Warehousemen's Union* (1962) 57 Cal.2d 781; *White v. Cox* (1971) 17 Cal.App.3d 824. This limitation is codified with respect to members of nonprofit associations. Corporations Code Section 21102 provides:

> No presumption or inference existed prior to September 15, 1945, or exists after that date, that a member of a nonprofit association has consented or agreed to the waiving of any obligation by the association, from the fact of joining or being a member of the association, or signing its bylaws.

See also, Corporations Code §§21100 (acquiring realty); 21101 (assuming debt or liability); 21200 (medical associations). Therefore, it would appear under California law that the potential liability of medical staff members is substantially the same whether or not the staff is recognized as a separate entity. The only additional exposure which results from the recognition of the medical staff as an entity is the potential for a judgment entered against the *association's* assets.

Is the separate staff an antitrust risk?

This result almost certainly obtains as well in the antitrust area. It is suggested that elimination of indications of the medical staff's separate identity will better enable the hospital and the medical staff to avoid liability on the theory that a single entity cannot conspire with itself. See, e.g., *Harvey v. Fearless Farris Wholesale, Inc.*, (9th Cir. 1979) 589 F.2d 451. However, an analysis of the recent cases considering the "intraenterprise conspiracy exception" suggests that the exception depends on the economic realities of the particular situation, not the formal designation of an organization as a separate legal entity. As the court stated in *Virginia Academy of Clinical Psychologists v. Blue Shield of Virginia* (4th Cir. 1980) 624 F.2d 476, "It is not enough to assert, as defendants do, that a corporation cannot conspire with itself. We must look to substance rather than form." The courts have refused to hold related corporations liable under the antitrust laws where it can be shown there is no conspiracy. See, e.g., *Harvey v. Fearless Farris Wholesale, Inc.* (no conspiracy where single individual who was president of both parent and subsidiary corporations was sole decision-maker) and *Seglin v. Esau,* CCH Trade Regulation Reporter ¶65,835 (hospital and medical staff were acting as a single entity for purposes of the antitrust laws). Moreover, they have refused to extend the intraenterprise immunity exception to a single corporation where the particular situation suggested that antitrust scrutiny was warranted. See, e.g., *Hahn v. Oregon Physicians' Service,* (9th Cir. 1982) 689 F.2d 840 (no immunity where physician competitiors have substantial control over corporation activities); *H&B Equipment Co., Inc. v. International Harvester Co.*, (5th Cir. 1978) 577 F.2d 239 (no immunity where agent has an independent personal stake in achieving object of conspiracy.) But see *Smith v. Northern Michigan Hospitals, Inc.* (6th Cir. 1983) 703 F.2d 942 (questioning whether personal stake exception applies in 6th Circuit.) Thus, medical staff members almost certainly may be held liable for the anticompetitive conduct in which they participate whether or not the medical staff is treated as a separate entity.

Moreover, it is unlikely that individual members of an unincorporated association will be held personally liable under the Sherman Act for activity in which they did not participate. Liability under the Sherman Act is generally determined with reference to legal principles applicable during the late 19th century when the Sherman Act was enacted. *American Society of Mechanical Engineers v. Hydrolevel Corp.* (1982) 456 U.S. 556, 568. At common law, members of unincorporated associations were generally not liable for the association's debts absent demonstration of personal participation. See "Comment: Liability of Members and Officers of Nonprofit Unincorporated Associations for Contracts and Torts," 42 California Law Review 812, 817-820 (1954); *United Mine Workers of America v. Coronado Coal Co.* (1922) 259 U.S. 344, 402 (suggesting that only assets of organization may be subjected to judgment where participation by individual members of association is not shown).

The case of *Weiss v. York Hospital* (M.D. Pa. 1982) 548 F.Supp.1048, (appeal pending) cited as providing "dramatic evidence" of the increased potential for antitrust liability if the staff is treated as a separate entity, does not change the foregoing analysis. Liability in the *Weiss* case was *not* predicated on a finding that the hospital had conspired with the medical staff. To the contrary, the medical staff and the hospital were each held liable for *separate* violations of the Sherman Act. Consistent with the jury's answers to special verdict questions, the court found the medical staff liable for a violation of Section 1 of the Sherman Act and the hospital liable for violations of Section 2. *Id.* at 1060-1061. Moreover, language in the opinion supports the conclusion that only the assets of the medical staff as an entity would be available to satisfy the judgment. The court rejected that portion of plaintiffs' request for injunctive relief which would have required individual members of the medical staff to agree to be bound by the court's order:

> No authority is stated for the proposition that this Court can bind persons who are not parties to this lawsuit in the situation where those non-parties are not acting in concert with parties to this lawsuit. Indeed the Court doubts such authority exists. [Citation] *Id.* at 1060.

Whether the staff is "separate" or not, medical staff members will generally be personally liable only to the extent they participate in the wrongful conduct. Hospitals are similarly unlikely to gain any advantage from treating the medical staff as a non-entity. Potential antitrust liability will depend on the circumstances of the particular case, not on formalistic considerations of whether or not the medical staff is a separate entity.

The law requires a "separate" staff

It is clear that the medical staff *must* be organized so as to be separate from the governing board. JCAH standards, Medicare and Medicaid regulations, California hospital licensing statutes and regulations, and statutes governing the practice of medicine in California all *require* that the medical staff be separate "organized." Relevant provisions include:

1. JCAH, Accreditation Manual for Hospitals (1984 Edition)

   Medical Staff Standard 1: There is a single *organized medical staff* that has overall responsibility for the quality of the professional services provided by individuals with clinical privileges, as well as the responsibility of the accounting therefore to the governing body.

   Medical Staff Standard 3: The medical staff is organized to accomplish its required functions.

2. Medicare and Medicaid Conditions of Participation

   42 CFR §405.1023, 42 CFR §440.10: The hospital has a *medical staff organized* under bylaws approved by the governing body, and responsible to the governing body of the hospital for the quality of all medical care provided patients in the hospital and for the ethical and professional practices of its members.

3. California Hospital Licensing Statutes and Regulations

   a. *Public Hospitals:*

   Health and Safety Code Section 32128: The rules of the hospital, established by the board of directors pursuant to this article, shall include: 1. Provision for the organization of physicians and surgeons, podiatrists, and dentists licensed to practice in this state who are permitted to practice in the hospital into a *formal medical staff,* with appropriate officers and bylaws and with staff appointments on an annual or biannual basis ... 3. Provisions that *the medical staff shall be self-governing* with respect to the professional work performed in the hospital. ...

   b. *Private Hospitals:*

   Health and Safety Code Section 1250(a): "General acute care hospital" means a health facility having a duty constituted governing body with overall administrative and professional responsibility and an *organized medical staff* which provides 24 hour inpatient care ...

   c. *Hospital Licensing Regulations:*

   22 California Administrative Code Section 70701. (a) The governing body shall: (1) Adopt written bylaws in accordance with legal requirements and its community responsibilities which shall include but not be limited to provisions for:

   (D) *Formal organization of the medical staff* with appropriate officers and bylaws.

   * * *

   (F) *Self-government by the medical staff* with respect to the professional work performed in the hospital. ...

   22 California Administrative Code Section 70703: (a) Each hospital shall have an *organized medical staff* responsible to the governing body for the adequacy and quality of the medical care rendered to patients in the hospital.

4. *Statutes governing the practice of medicine in California:*

   Business and Professional Code Section 2282: The regular practice of medicine in a licensed general or specialized hospital having five or more physicians and surgeons on the medical staff, which does not have rules established by the board of directors thereof to govern the operation of the hospital, which rules include, among other provisions, all the following, constitutes unprofessional conduct:

   (a) Provision for the *organization of physicians and surgeons* licensed to practice in this state who are permitted to practice in the hospital *into a formal medical staff* with appropriate officers and bylaws and with staff appointments on an annual or biennial basis.

   * * *

   (b) Provision that the *medical staff shall be self-governing with respect to the professional work performed in the hospital* ...

   Business and Professions Code Section 2400: Corporations and other artificial legal entities shall have no professional rights, privileges or powers.

There can be no question, particularly in California, that the law requires an "organized medical staff" which is "self-governing" with respect to the professional work performed in the hospital.

Can it be that the staff has no members:

Showing how far they are willing to carry their attack on the medical staff, Horty and Springer suggest that medical staff bylaws should not refer to members of the medical staff as "members" who have "joined" the medical staff, but rather as "medical staff appointees," because this phrase "more accurately reflects the process by which the physician is granted privileges."

The term "medical staff member" is used in every major codification of hospital standards including the JCAH Accreditation Manual for Hospitals and the Medicare and Medicaid Conditions of Participation. The continued use of this phrase is mandated not only by widespread custom and usage but because contrary to the assertion discussed above, the term "medical staff member" is more descriptive of the application and appointment procedure. A physician is not merely "appointed to the staff by the Board of the hospital."

Medical staff bylaws must contain elaborate procedures for the evaluation of medical staff applicants including formal appeal mechanisms. See, e.g., JCAH, Medical Staff Standard (I)(B), Medicare and Medicaid regulations 42 CFR §405.1023 subd (d) and (i); 42 CFR §440.10; 22 California Administrative Code §70703(b). While the governing body makes the final decision on medical staff applications, this decision ordinarily may not be made until the medical staff has completed its review and made a recommendation. For example, the JCAH Accreditation Manual provides in pertinent part:

> "The governing body requires the medical staff to make recommendations concerning medical staff appointments, reappointments, termination of appointments, and the granting or revision of clinical privileges.
>
> 1. Any differences are resolved within a reasonable period of time by the governing body and the medical staff.
>
> 2. The governing body acts on the recommendations."
>
> Governing Body, Standard I(K)

This elaborate procedure is far more akin to that utilized by selective membership organizations than it is to a mere "appointment" process. Finally, continued use of the term "medical staff membership" is necessary to clarify the distinction between general membership rights and specific practice privileges.

Can the staff elect its officers?

Horty and Springer also say that medical staff officers, department chairmen, and committee chairmen should be appointed by the governing body or, if elected, should be elected subject to the approval of the governing body. Such a requirement cannot be reconciled with California law. As discussed previously, hospital licensing statutes and regulations require that the medical staff be "self-governing with respect to the professional work performed in the hospital." The right to elect medical staff officers and department and committee chairmen would appear to be at the very heart of the right to "self-governance," and not subject to abridgment.

Here again, cases have been cited as threatening liability. Once more the cases cited as justifying board appointment or veto power do not support the argument. The question in *Wilson v. McCarthy* (App.Div. 1977) 393 N.Y.S. 2d 770 was whether the chief of the obstetrics department could be examined as to his expert opinion concerning the treatment rendered by one of the members of his department. The court concluded the department chief could be so examined because he could be held individually liable if the injury resulted from a negligent failure to develop or enforce adequate departmental procedures. There is *no* indication that the hospital was even named as a defendant in the case, much less that the hospital was required "to answer for [the department chairman's] actions."

The second case, *Johnson v. St. Bernard Hospital* (Ill.App. 1979) 399 N.E.2d 198 also does not stand for the proposition which is ascribed to it. The issue in the *St. Bernard Hospital* case was whether a hospital could be sued if the *hospital administrator* made no effort to help a physician obtain an orthopedic consultation, despite a medical staff bylaw which provided:

> Urgent consultation shall be answered within 24 hours from the time requested, and all other consultations shall be answered within 48 hours. After 48 hours if consultation is not answered, administration shall be notified.

The court did *not* hold that the hospital could be held liable if the department chairman failed to meet his duty to provide consultation. Indeed, in another portion of the opinion, the court expressly held that the hospital *could not be held liable* for the negligence of a physician who was not employed or paid by the hospital. *Id.* at 203. The court concluded only "that the hospital had a duty to use reasonable efforts to assist Dr. Thapedi in obtaining an orthopedic consultation." *Id.* at 206. The hospital could be held liable because of the *hospital administrator's negligence* in failing to take any action to enforce the requirements imposed by the bylaws.

How about subjective membership requirements?

Discussing membership requirements, Horty and Springer suggest that clinical privileges be extended only to persons who "behave appropriately in hospital settings." We wonder what they mean. Courts in virtually every jurisdiction have concluded that physicians have a right "to practice a lawful profession." This right substantially limits a hospital's discretion to exclude physicians. The protection afforded this right is both substantive and procedural. Generally speaking, hospitals may not exclude physicians based on arbitrary or discriminatory standards, nor may they exclude any physician without affording basic "due process," that is, notice and a hearing (called a "fair procedure" in California).

California courts have specifically held that there must be a demonstrable nexus between the standards for medical staff membership adopted by the medical staff and the hospital and the provision of quality patient care. See, e.g., *Miller v. Eisenhower Medical Center,* (1980) 27 Cal.3d 614. It is extremely unlikely that California courts would uphold an exclusion based on a bylaw requiring physicians to "behave appropriately." The courts have specifically rejected bylaws requiring that the applicant be able to "get along with others" and be "tempermentally and psychologically suited for cooperative staff-hospital functions," (*Rosner v. Eden Township Hospital Dist.* (1962) 58 Cal.2d 592) and they have upheld bylaws requiring that physicians be able to "work with others" only when interpreted to require a showing that the inability poses "a real and substantial danger" to quality patient care. *Miller v. Eisenhower Medical Center.*

Peer review hearings: can the staff be trusted?

Taking another cut at staff responsibilities, Horty and Springer also suggest that the bylaws permit the use of laymen on the hearing panel and that the hearing panel always be appointed by the hospital. These are dangerous recommendations. Regular recourse to non-staff physicians would raise serious confidentiality and liability problems. Aside from the practical difficulty of maintaining confidentiality when individuals outside the medical staff are involved, it is unclear whether the legal protections ordinarily applicable to medical staff committee proceedings would apply. The discovery protections of Evidence Code Section 1157 and the conditional immunity provision of Civil Code Section 43.7 apply only to organized committees of the medical staff. Second, it is unclear whether the use of non-physicians on the hearing panel would comport with "fair procedure" requirements. California courts have repeatedly cited the JCAH and CMA/CHA guidelines for hearing and appeal procedures with approval as evidence of the formal requisites of a "fair procedure." See, e.g., *Anton v. San Antonio Community Hospital* (1977) 19 Cal.3d 802, 818 (taking judicial notice of JCAH "Guidelines for the Formation of Medical Staff Bylaws, Rules and Regulations (1971)) and *Marmion v. Mercy Hospital and Medical Center* (1983) 145 Cal.App.3d 72 (discussing CMA-CHA Uniform Code of Hearing and Appeal Procedures). Both JCAH and CMA/CHA guidelines require that the physician receive a hearing before his "peers." The real vice in this approach is that it ignores the professional element which the medical staff should—according even to the *Johnson* and *Elam* cases—supply to the hospital.

Who dictates the bylaws?

It is suggested that the responsibility for review and amendment of the medical staff bylaws be removed from the medical staff and lodged with the board and "experts." This suggestion ignores the status of bylaws as a bilateral agreement. The only reported decision ruling on the legality of unilateral bylaws amendment by a hospital board concluded that a hospital board was legally prohibited from amending the medical staff bylaws unilaterally. In *St. John's Hospital Medical Staff, et al. v. St. John Regional Medical Center* (S.D. 1976) 245 N.W.2d 472, the Supreme Court of South Dakota struck down bylaws which had been unilaterally adopted by the board and not approved by the medical staff as null and void. The court based its conclusion on the fact that the medical staff bylaws contained provisions requiring that amendments be adopted by the staff and approved by the board. The *St. John's* case will almost certainly be followed in California. Our September 7, 1983, letter on this topic discusses this issue in greater detail and has been distributed to medical staffs.

The right to separate counsel

Finally, Horty and Springer do battle with the notion that medical staffs may consult their own attorneys.

The associational rights of individuals are protected by the First Amendment of the United States Constitution. *NAACP v. Button* (1963) 371 U.S. 415. This protection clearly extends to the right of an association to seek legal advice, *Brotherhood of Trainmen v. Virginia* (1964) 377 U.S. 1; *United Mine Workers v. Illinois State Bar* (1968) 389 U.S. 217; and *United Transportation Union v. Michigan State Bar* (1971) 401 U.S. 576, and would appear to prohibit a public hospital from denying a medical staff access to an attorney. We believe the California courts would extend this right to the medical staffs of private hospitals as well. It is necessarily concommitant to the medical staff's right of self-governance and the right of individual physicians to practice a lawful profession. In earlier communications, we have addressed the medical staff's right to consult separate legal counsel in detail. We will not repeat that analysis here. We do observe that telling medical staffs they cannot consult separate counsel is guaranteed to produce confrontation. The position is not legally supportable, and ignores inevitable reality.

Conclusion

An advocate's task is to present his client's point of view as favorably as he can, advancing his client's objectives. Some hospital administrators and some trustees may welcome the advice Horty and Springer and a few others are now offering. Until one examines the legal justification for the proferred advice, it may sound plausible. Even those trustees and administrators who see the dangers in usurping the professional role and responsibilities of the medical staff may believe that there is legal compulsion that they do so. When the cases are examined, it becomes apparent there is no such compulsion. In the final analysis, the hospital is better served by a functioning, properly organized medical staff. Self-governance is not inconsistent with mutual commitment to quality medical care. Certainly, hospitals can no longer contend that the hospital has no responsibility for the quality of care rendered by the medical staff. Numerous mechanisms are available to the Board to require the medical staff to discharge its professional responsibilities. The notion that self-governance must be sacrificed to obtain this mutual goal is simply without foundation.

Needed: A New Way to Train Doctors

(Second of Two Parts)

DEREK BOK

The Nature of Reform

General Goals: Before examining what kinds of changes medical schools might consider, let us remind ourselves of the several aims that educational reform should strive to achieve.

The most obvious goal is to make improvements in medical education that will increase students' ability to serve their patients well after they become doctors. One important way of achieving this aim is to give more attention to neglected areas of knowledge, such as ethics, patient psychology, computer applications, or methods of prevention. But it is also useful to search for better ways to train students to perform traditional tasks. Despite the progress in medical science and technology, many studies have revealed that doctors make a disturbing number of major diagnostic errors. For example, a recent survey of 100 autopsies at a prominent teaching hospital disclosed such mistakes in 22 percent of the cases.[24] In almost half of these instances, a correct diagnosis would have indicated a change in the treatment that might have prolonged life. Other studies have shown erratic performance in carrying out routine tasks. Thus, a survey of 249 patients in the outpatient clinic of a teaching hospital revealed that internists often neglected simple high-yield procedures such as examining the prostate or asking for a urinalysis (omitted 20 percent of the time), ordering blood-sugar analysis (omitted 30 percent of the time), and testing the stool for blood (omitted 40 percent of the time).[25] According to the authors, "The internists who failed to perform these simple high-yield procedures were at the very least unsystematic and at the worst neglectful."[26] Training students to be more thorough and more skillful in carrying out such tasks may reduce the number of errors and improve patient care.

Beyond helping students become more proficient, faculties should try to avoid making the educational experience more disagreeable than it needs to be to accomplish its purposes. At present, medical schools are not pleasant places for all of their students. This much emerges clearly from accounts by students and faculty alike. After all, what is one to make of the long-standing complaints over the pressures felt by undergraduate premeds and the tedium and frantic memorization associated with the preclinical years? Persistent dissatisfaction on this scale hardly seems inevitable. Nor is it fair to justify the status quo as some sort of test or initiation rite that will strengthen the character of students. On the contrary, there is good reason to look for ways to improve on the present situation, for the time given to medical training takes up years of a human life, years that have a value quite apart from whether a better doctor emerges at the end.

Finally, medical schools must do their best to prepare students to address the problems afflicting our health care system. As we have seen, these problems are serious. In particular, 28 million people still lack reasonable access to medical services, yet the total bill for health care in this country is already enormous and continues to climb much faster than the cost of living. No consensus has yet emerged on how to overcome these deficiencies.

No country believes more strongly in higher education than the United States, and no country is quicker to attribute national problems to failings in our universities.

We must be careful not to expect too much of medical training in our search for effective solutions. No country believes more strongly in higher education than the United States, and no country is quicker to attribute national problems to failings in our universities. Business schools are blamed for our declining competitiveness abroad, schools of education for the sagging performance of our youth on standard achievement tests, law schools for the surfeit of litigation. In reality, however,

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the causes are almost always more complex. Medical schools cannot ensure proper care for the millions not covered by existing public and private programs. Nor are they well equipped to prescribe how many doctors the nation needs. No single institution can do much to limit the supply of new physicians or persuade them to work in underserved rural areas. Contrary to popular belief, careful studies even suggest that neither medical school teaching nor the nature of the curriculum has much effect on decisions by students whether to enter primary care as opposed to specialty practice or academic medicine.[27] While medical faculties can play a modest supplementary role, only government can devise the policies we need to ensure a proper number and distribution of doctors.

Medical schools can make more significant contributions along different lines. To begin with, faculties can offer better instruction in preventive medicine. Up to half of all illness in the United States could be avoided through changes in behavior brought about by voluntary adjustments in lifestyle or by preventive measures on the part of government and private organizations. The latter are primarily the responsibility of the state, acting through appropriate rules and incentives. But education and persuasion can bring individuals to avoid smoking, excessive drinking, dietary deficiencies, inadequate exercise, unknowing exposure to health hazards, and many other forms of dangerous behavior. In this endeavor, the media and the schools have important roles to play. But physicians have a special competence to discover risks that patients unwittingly run in their daily lives. They also have a special status and authority that can help them persuade individuals to alter their habits. Yet prevention currently receives only 1.5 percent of the total teaching time in the medical curriculum. One should not exaggerate the impact of more instruction—we know too little about the process of changing human behavior. Even so, there is little doubt that doctors could learn to be more effective in detecting avoidable causes of disease, more competent in using epidemiological techniques to identify community measures for prevention, and more adept at persuading patients to minimize needless risks. With greater numbers of primary care practitioners and the growth of health maintenance organizations and other community-based institutions for health care, the opportunities for doctors to make such contributions seem destined to increase.

Faculties can also prepare physicians to curb inflated costs by eliminating needless medical tests and procedures. Individual practitioners typically make decisions involving diagnosis and treatment that call for expenditures of several hundreds of thousands of dollars each year. One cannot imagine a company in which executives could purchase goods and services in these amounts without knowing the price of what they bought. Yet recent investigations show that a majority of doctors do not know (within 25 percent) what laboratory tests actually cost.[28] Other inquiries have detected enormous variations among similarly situated physicians in the use of laboratory tests and the prescribing of drugs.[29] Fortunately, continued efforts to educate doctors about costs seem to produce impressive economies.[30] The potential savings are not trivial. Americans spend more than $25 billion each year on drugs and tests. Moreover, according to one presidential commission, unnecessary hospitalization may consume up to 20 percent of all hospital days; 50 to 65 percent of all antibiotics seem unwarranted or incorrectly administered; and billions of dollars are lost each year in useless chest X-rays or pointless respiratory-care treatment and tests.[31]

If we are to minimize such excesses, the government must fashion appropriate rules and incentives. But these initiatives will not work well unless physicians understand them and agree to cooperate. The success or failure of many regulations will depend on how they are implemented in hospitals, health maintenance organizations, and clinics, and those who direct these institutions are typically doctors. Moreover, the struggle to control medical costs in a manner consistent with proper care will ultimately be won or lost in a host of separate decisions that practitioners make in treating individual patients. On this battleground, the doctor will inevitably have the upper hand. No government inspector, no hospital trustee can readily overrule the judgment of a trained specialist in matters that involve the health and even the survival of human beings.

Finally, although physicians have great influence in treating individual patients, the public will be reluctant to pay the price of allowing everyone to have access to a health care system in which doctors are free to spend whatever they wish. For this reason, if we are ever to guarantee adequate health care to all, we must somehow find a way of joining the administrator's concern for reasonable cost with the physician's preoccupation with the needs of individual patients. This can hardly occur if doctors know nothing of costs and the problems of organizing and administering the health care system. On the contrary, medical schools must do their utmost to prepare physicians who have the understanding as well as the sensitivity and judgment to reconcile the need to serve the patient with the responsibility to avoid unnecessary expense.

Premedical Education: If reform is to go forward, it should start at the college level, for it is there that students first begin taking courses to advance their medical career. At present, the impact of medical schools on the undergraduate curriculum is, in Lewis Thomas's words, "baleful and malign."[32] Some premed students are competitive to the point of alienating their fellow undergraduates. Many change their courses and extracurricular activities to suit the supposed demands of medical admissions committees. All face requirements that bias them toward majoring in science and convey the misleading message that medicine, at bottom, is simply a matter of applying scientific knowledge.

In order to address these problems, universities will need, first of all, a change in attitude on the part of both medical schools and faculties of arts and sciences. Medical faculties fail to recognize that their admissions requirements are not simply private matters but policies that significantly affect the undergraduate experience. They should acknowledge this fact and accept an obligation to make their influence as benign as possible. Arts and sciences professors, because they dislike having students take their courses to fulfill another faculty's requirements, often turn their backs and teach their classes as though the premed requirements did not exist. This practice only makes matters worse, since the required courses come to include much material that cannot be considered truly necessary to the preparation of a doctor.

Medical school requirements are an undesirable intrusion on the college curriculum and should therefore be kept to a bare minimum.

A useful first step would be for representatives of both faculties to work in concert, first to agree on the minimum of knowledge needed to enter medical school and then to devise courses that cover the necessary material. Since students are forced to try to satisfy the requirements of all the schools to which they apply, an even better step would be to launch this effort on a broader basis under the auspices of the Association of American Medical Colleges. Discussions should proceed on the shared assumption that medical school requirements are an undesirable intrusion on the college curriculum and should therefore be kept to a bare minimum. This obligation implies a conscientious attempt to devise premedical courses that do not include material irrelevant to becoming a doctor. It also calls for a serious effort by the medical faculty to find space for important subjects in its own curriculum and avoid asking colleges to supply courses that medical schools themselves should offer.

Although it is hard to know what will come of such an effort, preliminary estimates in our own Faculty of Arts and Sciences suggest that the necessary scientific knowledge might be fitted into two year-long courses. Such compression would cut in half the time presently needed to fulfill the prerequisites for medical school. It would lower the requirements to a level approaching the amount of science that should be taken in any event by all undergraduates, whether or not they apply to medical school, as part of a liberal arts education. It would reduce the current pressure to major in science, since students concentrating in other fields could now fulfill their premedical requirements without using up virtually all their undergraduate electives. In these ways, such a modification would significantly lessen the distortions of the premed requirements on the educational choices of college students.

Another useful step for medical schools would be to cease the practice of expressly basing admissions in part on the applicant's grade average in science courses—the so-called science GPA. Granted, science is fundamental to medicine, and medical schools can scarcely be indifferent if an applicant does significantly worse in science than in other undergraduate courses. But the current practice conveys a message that science is all important and that the more taken, the better. No amount of verbal reassurance by admissions officers has served to alter this perception. The result is that many undergraduates take more science courses than they might otherwise have chosen in an effort to impress the admissions committees.

A final possibility would be for college faculties to develop more courses in the humanities and social sciences that involve medicine. Philosophy departments could consider a course in medical ethics. Economics departments might provide an offering in health care economics. History of science departments could give instruction in the history of medicine. Corresponding offerings are conceivable for departments of sociology, psychology, and even political science. Such courses are of interest to a wide range of students and can be taught in a manner thoroughly in keeping with a liberal arts education. They offer a broader view of medicine that should help undergraduates make more informed decisions about whether to pursue a medical career. They may also convey the useful message that medicine is more than science and help aspiring doctors adjust to a world in which their profession will need to cope with a wider set of pressures and concerns.

Preclinical Education: The principal aim in improving the preclinical curriculum should be to do what other professional schools did many years ago: reduce the amount of factual information conveyed in the classroom and employ teaching methods that emphasize problem solving and the mastery of basic principles rather than memorization of detail. In order to reach this goal, basic scientists and clinical faculty must work together to agree on the basic concepts and material that students need to learn. The number of lectures should be sharply cut back, and professors should teach their material as much as possible through problem-based discussions, tutorials, computer-aided instruction, and other methods that actively challenge their students and teach them how to learn by themselves. Finally, professors should amend their examinations to conform with the new objectives by testing the students' powers of analysis and not simply their ability to recall vast quantities of information.

By taking these steps, a faculty could enhance students' interest, improve their ability to reason creatively and rigorously, and soften the jarring contrast between the intellectual stimulation of the last years of college and the tedium produced by endless lectures and constant memorization in the preclinical years. Faculty members may object that such reforms will cut out too much scientific information that is important to physicians and essential for passing the National Boards. But these objections are shopworn and unconvincing. Information that is truly important can be communicated in written form. There is no reason to waste the limited resource of classroom time by repeating the material orally. Moreover, one must be skeptical about expansive definitions of "essential" information. With advances in science, much of what seems essential today will be outmoded tomorrow. Dean Burwell was only partly facetious in stating to Harvard medical students: "Half of what we have taught you is wrong. Unfortunately, we do not know which half."

Many experiments have likewise shown how little information students actually recall from lectures a week, a month, a year after they are given. According to Duncan Neuhauser, a recent study at Case Western Reserve has found that second-year students will have forgotten 90 percent of the factual items they have learned by the time they graduate.[33] Worse yet, cognitive scientists tell us that learning lots of factual details often makes it more difficult to remember the really important concepts.[34] These findings suggest that preclinical teachers will do better to concentrate more on helping students master fundamental ideas by actively discussing how to apply them in various contexts.

Furthermore, to echo a host of distinguished critics from Abraham Flexner to Michael Bishop, the most important reason for teaching basic science is not to convey quantities of facts but to instill a set of *attitudes* that will carry over into clincial practice—a taste for defining problems, creating hypotheses, and testing them rigorously. What disappoints these critics is that the very effort to cram "all the essential information" into the heads of passive students tends to produce the very opposite of the active, inquiring scientific mind that every physician should possess.

Even if the faculty acknowledges the need for reform, the necessary changes may be long in coming. Professors will find it hard to agree on which concepts and knowledge are truly fundamental and which can be cut away. This is a daunting task under the best of circumstances. It is made more difficult by the fact that many basic scientists have little idea of what a practicing doctor needs to know and regard efforts to reduce the number of lectures they give as a sign of disrespect for their subject. The challenge of mastering new methods of pedagogy is also formidable. Many professors *think* that they can teach by the discussion method. If one observes them, however, they often do little more than ask true/false questions that test students' memory rather than challenge their powers of reasoning. Instructors are also inclined to give the answer when the correct response does not come quickly from the class, thus depriving students of the valuable experience of struggling through to a conclusion by themselves.

It is no simple matter to prepare a faculty to use new forms of instruction, especially when they have few good models to remember from their own student days. Fortunately, however, much progress has been made in training people to teach. Not only can one find written materials or develop seminars for the purpose; even better ways have been developed through the use of videotape to enable instructors to observe themselves in the act of teaching with the help of an experienced critic. Through these techniques, most people can make surprising progress in perfecting their ability to lead a stimulating discussion. All that remains is to find the motivation and the will—and those are ingredients that must be supplied by leadership backed by adequate rewards.

The preclinical years are also the time to begin an effort to expand the students' knowledge by introducing subjects such as medical ethics, psychology, statistics, computer use, and formal methods of decision making. We have seen how important these subjects have become in enabling physicians to discharge their responsibilities. Experience also suggests that able teachers can accomplish much to help students acquire competence in these fields. It is certainly possible to train people in the uses of statistics, computers, and formal methods of decision making. As for medical ethics, no one could pretend that a course can turn every aspiring physician into a virtuous human being. Even so, competent instruction using cases and discussion can help students become proficient in perceiving ethical dilemmas when they arise and in thinking about them in a manner that is rigorous and informed. Well-conceived courses can also acquaint students with the causes of rising medical costs and the methods for trying to bring them under control, just as training in cost-benefit analysis and better strategies for acquiring information can help students learn how to minimize unnecessary expense in caring for patients.

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The teaching of psychology may present greater difficulty, since so many complexities of human behavior are still beyond our understanding. Even so, students can certainly be taught to talk more clearly and persuasively to patients about medications and treatments. Instructors have likewise shown that they can train students to interview more effectively and to improve their skill in detecting significant psychological and cognitive disorders. At a deeper level, students can also learn the elements of what is known about the impact of psychological and social factors on human illness and rehabilitation, not to mention the effects of personality factors on the willingness of patients to cooperate fully with physicians.

Most faculties already offer courses on almost all these topics. The problem is to assign them their proper place in the curriculum. In the ethos of the contemporary medical school, with its strong emphasis on biomedical science, subjects such as decision analysis, statistics, patient psychology, ethics, and health care policy must be required and given ample time if we expect more than a small minority of students to study them seriously. Faculty members will complain that there is no room to force these courses into an overstuffed curriculum. Students will resist any inroads on their opportunities to take electives. Yet space can and must be found, whether it comes from elective slots or from the time freed up by pruning unnecessary detail from the basic science courses. After all, many faculties have experimented with a three-year curriculum, and doubts are often expressed at other schools about the value of the final year of study. These straws in the wind suggest that room exists to substitute new material for existing courses if such changes are important to serve the needs of medical practice. The subjects just described surely meet this test. No longer peripheral, they have moved toward the center of our emerging vision of how physicians must think in order to function effectively in the modern world.

Clinical Instruction: The great strength of the clinical years is the vivid reality that comes with learning in the hospital and caring for the sick. Nothing holds students' attention more raptly or motivates them more strongly than the presence of real patients in need of help.

Yet the very strength of the clinical years is also the source of their greatest problems. Since much of the teaching takes place in the hospital, its content is shaped by the exigencies and peculiarities of patient care. What students learn typically depends on the ailments of the patients who happen to be in the ward at that moment—and in a teaching hospital these ailments are likely to be far more complicated and rare than those that ordinary doctors see in community hospitals and ambulatory settings. The quality of intruction on the ward also reflects the overriding responsibility for patient care. Those who teach, especially the house staff, are often weary from their responsibilities and subject to interruption at any time to serve some compelling patient need.

The principal problems of clinical teaching, then, are rooted in imperatives of care that can easily lead to improvisation and a lack of orderly structure. Adequate structure requires that each rotation have clear objectives fixed in advance to define the basic material and skills that students should master. Adequate structure means that ways are devised and ample time provided to convey the desired material and teach the designated skills within the period of the rotation. Finally, adequate structure implies that students know the objectives in advance, receive reasonable feedback to monitor their progress, and obtain sufficient evaluation to see whether they achieved the goals prescribed. Too often these qualities are lacking on the wards of our teaching hospitals.

Similar problems are evident in the style of clinical instruction. Walking through hospital corridors, one is struck by the variable, unrehearsed quality of the teaching. Sometimes patients are seen and talked to, sometimes not. Bits and pieces of information are conveyed on the spot as problems develop and new data arrive from the laboratory or the night nurse. Much information is conveyed didactically or demonstrated at the bedside. Instructors do pose questions to students on occasion, but usually to test their knowledge rather than to train their powers of analytic thought. Too rarely does one hear a genuine, sustained dialogue that challenges students to elicit relevant data, venture hypotheses, and move toward a final diagnosis by trial and error. Ethical issues, cost considerations, psychological problems—all pop up occasionally but seldom receive thorough discussion. House staff and faculty specialists are rarely well versed in these subjects and often lack time to discuss them in detail amid the pressing responsibilities of patient care.

It is difficult to overcome these problems fully in the context of a teaching hospital with its bustle of busy people and its compelling, unpredictable demands. Yet even in this setting, something can be done to achieve greater structure. Senior faculty can set objectives that are understood by all and offer adequate opportunities for feedback and evaluation (as Harvard departments have tried to do in recent years). Required readings and occasional lectures can help ensure that basic information is conveyed and understood.

Although these measures are useful, the tensions inherent in clinical teaching will become more acute as faculties accept the need to broaden their training to place more emphasis on subjects such as ethics, patient psychology, prevention, and cost-effective strategies for making diagnoses and prescribing proper treatments. Many studies have shown that integrating such material into clinical training is essential if these subjects are to make any lasting imprint on the minds and behavior of medical students. But patients who happen to enter the hospital may not have problems that illustrate the topics in optimal fashion, nor will the house staff always have the ability to teach such subjects well. To some extent, these difficulties can be overcome by more readings and seminars and by extending clinical instruction to ambulatory settings that expose students to a broader range of human afflictions. Still better would be some pedagogic method that could serve the needs of order and structure without giving up the vivid realism of actual patient care.

Simulations of various kinds offer useful ways to help surmount this problem. Whether the simulation takes the form of a written script or uses actors who play the part of doctor and patient, students can learn to ask appropriate questions, frame hypotheses and test them until a correct diagnosis can be found. The same method can be transferred to a computer with the great advantage of allowing each student to practice as much as desired at any hour of the day. Better yet, one can program the computer to ask questions of its own in order to form a Socratic dialogue that forces students to think more deeply and devise thorough but efficient strategies for obtaining the data to reach a proper diagnosis. Obviously, simulations cannot and should not replace the experience of serving and learning on the hospital ward, with its compelling immediacy and reality. As learning technology develops, however, it is not farfetched to assume that such methods will play an increasing role in helping faculties cover a body of important material that is growing too large and diverse to be fully and effectively captured in the hospital setting.

The Medical School's New Pathway

The preceding discussion has revealed something of the scope and range of current opportunities to improve medical education. A team of Harvard faculty and students is now at work devising a new curriculum, or pathway, to capitalize on many of these possibilities. Although the initial effort will be a pilot venture for only 25 students per year, participating faculty members hope that it will have enough success to exert a strong influence on the entire school.

The original plan was to overcome the arbitrary divisions into premedical, preclinical, and clinical education by having the College agree to an integrated curriculum that students could enter, without taking premedical courses, at the beginning of their junior year. The first two years of the program would have left room for ordinary college courses and might well have been as compatible with a liberal arts education as the experience of a typical premed majoring in science. But the proposal ran into strong opposition. Arts and sciences officials thought it too professional for the College. Virtually all medical students also protested, as did the medical faculty, fearing that such a program would force undergraduates to make career choices prematurely.

Although this opposition stymied plans to begin the program in the junior year, professors from both faculties are meeting to consider whether the premedical requirements can be reexamined and compressed into two full-year courses. College officials may also agree to highlight courses outside the sciences that involve the health professions and the health care system so that undergraduates are encouraged to gain a broader view of medicine than the traditional science prerequisites would allow. These reforms would do much to mitigate the problems of premedical education.

If the faculty is serious about nurturing attitudes, there remains much truth in Plato's observation: "If you would know virtue, observe the virtuous man."

In developing a curriculum for the Medical School itself, the principal architects were aware of the tendency in medical education to allow separate departments and disciplines to act in substantial independence from one another. This practice often contributes to a lack of coherence in the curriculum. To guard against this danger, the dean began by assembling a group of faculty members from various departments to devise a set of common goals in the form of a list of attitudes, knowledge, and skills that medical schools should impart to students.

A striking aspect of the list is the emphasis placed on the development of proper attitudes. As one would expect, many of the attitudes are hardy perennials: honesty, integrity, dependability, sensitivity, responsibility. But others are not so obvious: "capacity to be with the sick and suffering and remain open to their needs"; recognition of one's own limitations"; "recognition of how financial aspects of practice affect self, patients and society"; "recognition of the impact of power on self, patients and co-workers."

It is hard to think of another professional faculty, with the possible exception of theology, that would explicitly set about to nurture such attributes in its students. In part, the effort to do so may simply be a reflection of the awesome responsibilities of a profession that is often called upon to make decisions involving life and death. In part, the effort may be a response to signs of growing dissatisfaction over the quality of the personal interaction between doctors and their patients and coworkers. (For example, a study described in the recent Institute of Medicine report on medical education found that 64 percent of a large sample of families were unhappy with their doctor-patient relationship and that one-third to one-half of the families had changed doctors because of dissatisfaction over the physician's personal qualities.)[35] Whatever the reason, the desire to address these issues is commendable. The problem lies in figuring out just how the task can be accomplished.

Good teaching will undoubtedly achieve something. A skillful instructor can raise a student's consciousness, awaken interest, stimulate thought. But if the faculty is serious about nurturing attitudes, there remains much truth in Plato's observation: "If you would know virtue, observe the virtuous man." Any effort to teach by personal example, however, raises interesting problems of its own. Will instructors be chosen with an eye to their character and a concern for the extent to which they manifest the attitudes they seek to plant in their students? If so, the selection of faculty will call for delicate judgments that few people can successfully make and fewer still will accept with confidence. Without choosing teachers on this basis, however, one wonders how much the Medical School can accomplish in carrying out its laudable aims.*

Turning to areas of knowledge that the new curriculum will convey, one finds, at the top of the list, "an understanding of the central physical, chemical and biological principles and mechanisms that underlie human health and disease, including awareness of the natural history and manifestations of the diseases." The prominence given these traditional subjects should help to dispel any suspicion that the new curriculum is rejecting the centrality of science or training a special breed of doctors who will somehow escape the need to be thoroughly versed in biomedical knowledge. At the same time, the planning group goes on to specify a number of other goals that have been stressed in this report:

- –To understand the emotional, psychological and cultural underpinnings of human behavior, including the interweaving of mind and body in illness and health ...
- –To know the financial and organizational aspects of health care ...
- –To understand the various factors which contribute to the prevention of illness ...
- –An understanding of the statistical and probabilistic aspects of human biology and clinical medicine ...

The list of skills likewise reflects a desire to build the broader competence that physicians increasingly need. The planning group puts emphasis not only on obtaining information from printed material but on retrieving it from computers. Statistical and problem-solving skills will get particular attention in order to foster greater competence in acquiring relevant information, assessing its validity, and making sound probabilistic judgments. Discussions about the selection of appropriate diagnostic technology will be accompanied by explicit attempts to assess the costs and benefits involved.

In addition to these competences, the planning group has also listed the more familiar skills of listening, observing, interviewing, and communicating effectively. These tasks are always honored in principle but often slighted in practice, so much so that investigators have reported that medical students' ability to communicate actually deteriorates during their professional training.[36] Yet communication is bound to take on greater importance in the future as doctors allow their patients to participate more in deciding what chances to take with different tests and remedies and as higher priority is placed on motivating patients to follow treatments conscientiously and to avoid various kinds of life-threatening behavior. With such needs, one can only hope that the deliberate inclusion of these skills among the aims of the new curriculum presages an equally deliberate effort to teach them systematically.

Whatever its ultimate success, no one can fault the new pathway for having stunted ambitions. After reexamining almost every accepted premise about medical education, the participants seem committed to comprehensive change. Amid the details of innumerable planning memoranda, several themes stand out with special clarity. To begin with, the curriculum calls for a radical shift in teaching technique. Lectures will be cut to one hour per day in order to stress active discussion rather than the passive modes of learning so roundly criticized in the past. A strong emphasis on problem solving and independent study will help to overcome the static quality of medical education and to impart the capacity for continued learning that is needed to keep up with such a vast and rapidly changing body of knowledge. Properly executed, these changes should train students better and make their education much more stimulating.

In carrying out its work, the planning group has likewise acknowledged the forces that are currently working to broaden the physician's role and has reserved ample time in the curriculum to prepare students to cope with these new challenges. If the faculty can translate this time into effective instruction, students should receive an education that prepares them not only to serve their patients better but also to respond more effectively to societal needs.

Finally, participating faculty have sought to integrate the curriculum with the help of working groups that include professors from several different departments. By this device, scientists and clinical faculty can work together to break down the separation between the preclinical and clinical years. Through these efforts, the planners hope to bring out more clearly the relevance of basic science by stressing its links to clinical problems. Conversely, subjects such as statistics, cost containment, patient psychology, and prevention will not be treated merely in isolated courses but will reappear in the clinic where students can deepen their understanding of these important topics by discussing applications to real cases.

At this early stage, many questions remain unanswered. Who will teach some of the new material in decision making, ethics, patient psychology, and the like, for which qualified professors are in short supply? What steps will the faculty take to ensure that students actually learn these subjects? How will instructors manage to change their teaching styles and master the art of leading a genuine discussion? Will the rest of the faculty allow the use of rewards and recognition sufficient to induce professors to plunge wholeheartedly into this teaching effort? What will participants do to escape the tyranny of the National Boards with their emphasis on rote memory and factual detail? And how can the school evaluate the program convincingly when the criteria are necessarily vague and the skeptics quick to ascribe any student enthusiasm to the "Hawthorne effect" that tends to accompany any experiment conducted with a small group?

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*Some readers may believe that medical schools can best ensure proper attitudes by taking greater care in selecting students. In fact, most medical schools do interview applicants and try to give weight to traits of character such as those listed by the planning group. While these efforts are commendable, their impact is unclear. The interviewing process is sufficiently unreliable and the traits involved sufficiently intangible and easy to simulate that we have no reliable evidence that such procedures can have much effect on the characteristics of a medical school student body.

These are typical questions to arise in the development of a major educational innovation. They call for care in planning and execution but not for discouragement of any kind. The essential point is that the dean and a large group of faculty have recognized that basic changes are needed in medical education and are prepared to devote the time required to produce the necessary reforms. This is an event of great importance for the University and deserves our strongest encouragement and support.

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Month in Washington

Physicians Not Signing Up Early

By mid-September, only 10 to 12% of physicians had signed agreements to become Medicare "participating physicians," according to a survey by the Health Care Financing Administration.

The agency, which gave physicians until October 1 to choose whether or not to be participating or nonparticipating physicians, believes the proportion of participating MDs will increase as the deadline approaches.

To answer physicians' questions regarding the freeze and participating physicians provisions enacted this summer in the Deficit Reduction Act, HCFA established a hotline. The hotline, which will also handle calls about the act's laboratory reimbursement modifications, can be reached by calling 301-594-9504.

The participating physician provisions were the subject of a massive grass roots campaign by the American Association of Retired Persons. Calling them "one of the biggest health care cost control measures to come along for a long time," the 16-million member organization launched a nationwide campaign to encourage physicians to sign up for the new option.

Kicked off at a press conference with Congressional and Reagan administration participation, the campaign involved mailings to 30,000 AARP volunteer community leaders.

Responding to the AARP, American Medical Association Executive Vice President James Sammons, M.D., urged physicians to continue to accept or not accept assignment according to individual patient needs. He noted that the AMA has challenged the provisions in court.

* * * *

Bill to Discipline "Bad" Physicians Clears House Unit

The House Ways and Means Committee has approved a bill (HR 5989) that would expand the federal government's authority to act against physicians and other practitioners disciplined by state boards or sanctioned by Medicare and Medicaid.

Originally introduced in the Senate as S 2744 by Senate Aging Committee Chairman John Heinz (R-PA), the measure was introduced in the House by Rep. Henson Moore (R-LA) who said he hopes to see it enacted before Congress adjourns in October.

The bill stems from a General Accounting Office investigation recommending that Medicare and Medicaid be given authority to exclude any practitioner whose license had been removed by a state licensing board. It followed a GAO investigation which traced practitioners who lost their licenses in three states. One-third of these physicians held licenses in other states and at least 10% of them enrolled as Medicare or Medicaid providers in another state.

As approved by the committee, the measure excludes from Medicare and/or Medicaid any provider convicted of financial fraud or abuse of patients or controlled substances in connection with any state, federal or local health program. Any institution or entity whose owner, manager or director had been sanctioned by Medicare could also be excluded. The minimum exclusion is for five years.

The committee made several modifications in the proposal that had been approved by its health subcommittee. A requirement that state licensing boards inform HHS of all sanctions and license revocations imposed on health care practitioners was modified to permit HHS to acquire this from private agencies that already collect it. A provision permitting exclusion of providers failing to grant immediate access of records to the inspector general was changed to authorize suspension of payment rather than exclusion.

The modifications respond to suggestions of witnesses at a subcommittee hearing. American Medical Association Board of Trustees member Dr. John Ring criticized the exclusion authority against providers refusing access to records.

"Provisions such as exclusion for failure to grant the inspector general immediate access to records involve neither the professional fitness of the practitioner or any serious threat to the program involved," Dr. Ring said. Complying with administrative requirements of federal programs may be important, he added, but "they are a far cry from losing a license to practice medicine because of incompetence."

In other testimony, the inspector general along with the Federation of State Medical Boards of the United States, urged deletion of the requirement that states report disciplinary actions to HHS. They argued that voluntary organizations like the Federation already are maintaining a registry which the federal government could tap into.

* * * *

New Drug Approvals

The Food and Drug Administration approved the first antibiotic which actually eliminates the cause of bacterial resistance rather than simply boosting drug stability to bacterial attack.

FDA also approved a drug that improves blood flow through the plague-lined arteries of the arms and legs which should be available to physicians by October.

The new antibiotic, Augmentin (Beecham Labs), combines amoxicillin with potassium clavulanate. The potassium clavulanate eliminates a major cause of resistance, the beta-lactamase. The amoxicillin, with a second wave of action, kills the infection-causing organism.

The antibiotic combination combats a broad range of infection-causing bacteria implicated in sinusitis, lower respiratory infections and children's middle ear infections. Resistance to these bacteria has seriously impeded treatment.

Drug researchers traditionally try to combat the resistance problem by developing antibiotics such as the second and third generation cephalosporins, which show improved stability to attack by beta-lactamase.

The Augmentin strategy is different: the potassium clavulanate, with its high affinity for beta-lactamase, destroys the enzyme. The amoxicillin is then free to attack the bacteria. As a result, organisms which had developed resistance to amoxicillin due to beta-lactamase production are once again vulnerable.

The new drug for blood flow pentoxifylline, will be sold under the trade name Trental by Hoeschst-Roussel Pharmaceuticals Inc., of Somerville, NJ. It is expected to aid the roughly 1 million Americans afflicted with intermittent claudication, a condition caused by restricted blood flow to the extremities. The pain caused by lack of oxygen makes walking or other exercise extremely painful. The disease results not only from narrowing of the arteries but also from abnormal rigidity of the blood cells, increasing blood viscosity. In the past, little could be done to improve this type of circulatory problem.

However, pentoxifylline restores lost flexibility to rigid blood cells, enabling them to squeeze through small capillaries and supply oxygen to muscles. The drug is not intended to replace more definitive therapy, such as surgical bypass or removal of arterial obstructions. A total therapeutic regimen—combining the drug with walking, weight control, and a smoking cessation program—is recommended. Side effects such as upset stomach, nausea, dizziness, and headache may be noted.

While patients may feel benefits within two to four weeks, they should continue taking the medication for at least eight weeks. Continued treatment may show additional improvement.

* * * *

Congress Passes "Baby Doe" Bill

Both houses of Congress passed a "Baby Doe" bill agreed to earlier in the month by members of a joint House-Senate conference, and sent the measure to the President for his signature.

The bill, a compromise between versions passed by the House and Senate earlier this year, calls for the Department of Health and Human Services to draw up regulations setting guidelines for mandatory treatment of handicapped infants.

Treatment guidelines, the centerpiece of the bill, say that care should be withheld only when:

- the infant is chronically and irreversibly comatose,
- treatment would not correct all of the infant's life-threatening conditions,
- treatment would merely prolong dying, or
- treatment would be futile and inhumane

Thus, it does not require unending treatment when an infant is doomed to die, regardless of medical efforts. Nor does it require that physicians perform surgery for correctable defects, when another defect is lethal and untreatable. It also gives the parent the freedom, say the bill's sponsors, to make a "judgment call" when the child has little chance for survival.

However, it requires physicians to treat correctable defects without regard for the child's other handicaps.

State, not federal, governments would be responsible for ensuring that an infant is treated and fed. States would be required to set up a system of hospital representatives to report instances of medical neglect. States failing to comply would lose part of their child abuse funds.

The AMA resisted passage of the bill, saying it would require states "to intervene and second-guess the individual medical decisions made by parents, in consultation with physicians."

* * * *

HHS Refuses Deadline Extension on Medicare Sign-Up; AMA Sues

On September 20, the American Medical Association sent a telegram to Health and Human Services Secretary Margaret Heckler again calling for a delay in the government's deadline for physicians to sign up to "participate" in Medicare under the new Deficit Reduction Act.

"Physicians across the country have not been advised of their pattern of charges . . . nor have physicians been advised of the prevailing and customary charges which will determine their Medicare reimbursement and which must be known in order to decide whether to participate," AMA told Heckler. "There are thousands of physicians who cannot make an informed choice by October 1 whether to sign participating agreements nor can they be certain that they are in compliance with the freeze itself."

HHS lawyers replied that they didn't agree; that physicians have had plenty of opportunity to get the information they need to make the decision.

So the next day the AMA filed suit in the federal district court in Indianapolis along with a request for a preliminary injuntion to stay the October 1 deadline. The plaintiffs, in addition to AMA, are the Indiana State Medical Society and several physicians and Medicare beneficiaries from Indiana.

On Friday, September 28, the court denied the request for a temporary injunction to stay implementation of the October 1 deadline. However, Judge Sara Evans Barker did grant limited relief by extending the deadline to October 15 for physicians who had failed to receive as of September 28 complete Medicare information they had requested from Medicare carriers. The extension applies only to AMA or Indiana State Medical Association members.

A hearing on the main AMA suit challenging the constitutionality of certain provisions in the Deficit Reduction Act is expected to be scheduled soon.

* * * *

AIDS Is A Political Football

AIDS has become a favorite item of debate in Washington and a political football used by both the Reagan Administration and its Democratic critics on Capitol Hill.

The most recent dispute concerns research funding. Rep. Henry Waxman (D-CA) and city health officials in September demanded that more money be authorized to develop a blood test and vaccine for AIDS. Health and Human Services Secretary Margaret Heckler, on the other hand, contended that AIDS funding should come from other programs in the Public Health Service budget.

Rep. Waxman, who represents many gay voters in his southern California District, calls the Administration policy "negligent" and "reckless." "The result of such shortsightedness will only be a longer epidemic and longer deaths," he predicted in recent hearings of the Health Subcommittee.

HHS Secretary Heckler counters that fund-shifting is "the most effective way of providing additional resources for AIDS quickly."

The squabble began last May when HHS Assistant Secretary for Health, Edward N. Brandt, Jr., M.D., asked Secretary Heckler to request from Congress $20 million in additional funds. On August 8, Dr. Brandt received a letter saying his request for more money had been rejected. "With resources currently available to the Public Health Service, I direct you to carry out the most important projects of direct relevance to AIDS as soon as possible," Secretary Heckler instructed.

The Administration opposed new AIDS funds last year as well. Despite unanimous House approval and strong support in the Senate, the Office of Management and Budget opposed the addition of $12 million in new money and instead recommended that AIDS research funds be transferred from other programs within HHS.

Rep. Waxman, a longtime critic of the Republican Administration, has been particularly visible in his push for more AIDS funding.

Meanwhile, refuting allegations that it is moving too slowly against AIDS, The Reagan Administration is pushing ahead in its efforts to transform basic research findings into actual medical tools to fight the disease. Private research companies were given only 10 days to get their applications in for HTLV-III infected cells, which are needed to mass produce the virus and develop a blood test. Of 20 applicants, 5 were chosen to develop and distribute a blood test: Abbott Laboratories, Electro-Nucleonics Inc., Litton Bionetics, Inc., Travenol/Genetech Diagnostics, and DuPont Inc., with the collaboration of Biotech Research Labs.

Some companies already are testing blood at the rate of 1000 or so samples a day and have produced assays that take only hours to complete. Panels of sera, with varying levels of antibodies to HTLV-III, have been distributed by HHS to companies. Controlled studies using the sera will determine the tests sensitivity and specificity to the AIDS antibody.

Based on their findings, HHS will determine whether to license a test for commercial production. Blood banks will then decide which test is best suited for their needs.

The search for an AIDS vaccine is also moving at a fast clip. HHS officials are reportedly designing the criteria that must be met if a company wants access to the government's supply of HTLV-III cells. A number of companies which failed to win licenses for blood test production are said to be anxiously awaiting the chance to win rights for vaccine production.

* * * *

NAS Report on Premature Death for Survivors

Epidemiological studies now confirm what has long been suspected: the death of a spouse or close family member may result in premature death for survivors, according to a National Academy of Sciences report completed this month.

The 312-page volume, prepared after a two-year review of research studies and various institutions, is believed to be the nation's most comprehensive look at the bereavement process.

A number of studies reviewed in the report suggest that bereavement may enhance vulnerability to:

- Cardiac arrest. Sudden cardiac death, cardiac arrhythmias, myocardial infarction, and congestive heart failure are the most frequently mentioned conditions following the death of a close family member.

- Infectious disease. Grief—like stress, depression and panic disorder—may influence the body's hormonal milieu and cell-mediated immune mechanisms. Thus, by compromising the immune system, grief may alter the body's resistance to infectious agents.
- Neoplastic disease. Alternations in hormonal milieu following bereavement may have clinical importance to hormone-sensitive cancers such as estrogen-dependent breast cancer and testoterone-dependent prostatic cancers. Further studies are needed of ovarian, testicular and adrenal hormone regulation in bereavement and of the hypothalamic-pituitary stimulating hormones that control these target glands, the report states.
- Suicide. In some persons, the lonely circumstances of widowhood may predispose them to suicide. Others may have pre-existing characteristics, such as alcoholism or depression, that predispose them to kill themselves.

Some individuals are at greater risk than others following the death of a loved one, the report notes. Young and middle-aged widowers are most vulnerable to disease during the first year after death of a spouse and continue to be vulnerable for as long as six years if they do not remarry.

In general, bereavement reactions are more intense and have more enduring consequences for young people, particularly children in their early teens. Girls under 11 years who lose their mothers and adolescent boys who lose their fathers are at particular risk.

Persons who are physically or mentally ill before a bereavement are more likely to be ill after it; alcoholics more likely than non-alcoholics will be doing poorly one year after bereavement.

* * * *

New Cigarette Warning Label Set

Overcoming internal dissent, both the House and Senate this month passed new and explicit warning labels that stress the risks of cigarette smoking.

The measure was sent to the White House to be signed by President Reagan and will take effect one year after passage.

Once every three months, a package would contain a different warning: "Smoking causes lung cancer, heart disease, emphysema, and may complicate pregnancy"; "Quitting smoking now greatly reduces serious risks to your health"; "Smoking by pregnant women may result in fetal injury, premature birth, and low birth weight"; and "Cigarette smoke contains carbon monoxide."

In addition, the law would require manufacturers to tell the Department of Health and Human Services what additives their cigarettes contain.

Abandoned were warnings of "addiction, death, and miscarriages," strongly opposed by the tobacco industry.

* * * *

Final Regs on 1985 DRGs Released

Compromising with the hospital industry and Congressional critics, the Department of Health and Human Services has issued final regulations that will increase Medicare payments to hospitals in fiscal 1985 by about $300 million more than would have been the case under rules proposed earlier this summer.

The final rules, which govern the second year of Medicare's diagnosis related groups (DRGs) prospectice pricing system, also further modify the process for physician certification of the accuracy of the diagnoses in the hospital record. The primary change, however, involves an across-the-board reduction in DRG weights that has been cut from 2.4% in the proposed rules to 1.05% in the final reductions.

While the final regulations more than halves the proposed weight reduction, however, it also somewhat lowers the rate increase proposed earlier. Instead of a single 5.6% rate increase, the final regulations provide for a 5.2% increase in the federal portion (50% in 1985) of the Medicare payment and increases ranging from about 5.9% to 6.4% in the remaining hospital specific portion of the rate.

Published in the August 31 *Federal Register,* the final regulations also make further changes in the physician certifiction process which has been bitterly opposed by physicians since it first appeared in the final first-year DRG regulations published in January. Second-year regulations proposed in July made several changed aimed at reducing physician objections but many of the 4,000 comments received on the proposed rule were still dissatisfied with the certification proposal.

The July changes: removed from the hospital record a statement warning the physician of the consequences of a falsified record; required physicians' signatures on an annual statement acknowledging awareness of the penalties of fraud; required hospital certification on each claim that the signed statement was on file; and retained a modified requirement that the physician sign on each hospital discharge statement a statement attesting to the accuracy of a "narrative description" of the "principal and secondary diagnoses and major procedures performed."

The final rules retain the requirement that each record include the physician's signed attestation of accuracy. However, the hospital may now place the statement in any portion of the record. The signed fraud statement will still be filed, but the hospital need not include assurance of its existence on each claim. The narrative record may be generated by the hospital record-keeping department rather than the physician.

The President's Page

CMIC: A Beginning

After fifteen years in medical politics the events of the summer and early fall of 1984 have made me proud to be a member of my county association and the Connecticut State Medical Society. The leaders and membership of this great organization have taken a major step in controlling their own destiny and by so doing hopefully taking a small step in stabilizing ever increasing health care costs.

With the implementation of the Connecticut Medical Insurance Company the physicians of this state have shown that we are willing to come forth with our money and support to establish our own insurance company, operated and controlled by Connecticut doctors, with great hopes of getting command of a problem facing ourselves as well as our patients.

This action proves that we are willing to come forward and take the necessary steps to control our destiny. Although only a beginning, this move can and will pave the way for further physician involvement in all aspects of health care. It is imperative that our entire profession take part in this endeavor. It is my desire that over the next two or three years, all physicians in the state become members of this company and accomplish the task of making it one of the success stories of doctor owned companies which insure at least fifty percent of physicians in this country. By so doing we can achieve the greatest sense of unity our Society has had since its inception. We must encourage our fellow physicians to join us in this endeavor. With total support we can accomplish a great deal both in the stabilization of health care costs and other areas where attempts are being made to control our profession.

My fellow physicians and surgeons, I commend you for your action.

Joseph S. Sadowski, M.D.
President

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Reflections from the Dean's Office

Education and Costs

ROBERT U. MASSEY, M.D.

> "It is true in medicine, as in other fields, that the best is eventually the least expensive and that generally, therefore, cost is directly related to quality." [1]

Related in an unexpected way according to the Committee on the Costs of Medical Care, whose 1932 report concluded with recommendations for "basic educational improvements." To prevent is better and usually cheaper than to treat; to cure better and cheaper than to care for.

If costs are measured by more than dollars, I suspect that most of us would agree that in medicine costs and quality may be inversely related, and further, that the quality of medical care depends upon the quality of medical education.

Just as the 1932 report blamed some of the difficulties in medicine, including costs and the oversupply of specialists, upon "the character of medical education," [2] so those in industry and government who today are most concerned about the costs of medical care must come to see the roots of some of these problems, and therefore their remedies, in the character of medical education. Their recommendation might then be similar to this one of 50 years ago:

> "That the training of physicians give increasing emphasis to the teaching of health and the prevention of disease; that more effective efforts be made to provide trained health officers; that the social aspects of medical practice be given greater attention; that specialties be restricted to those specially qualified; and that postgraduate educational opportunities be increased;" [3]

What instead they are trying to devise is a complicated scheme of wage and price controls, a kind of strategy which has rarely provided more than temporary relief. It may be the only course of action which is politically acceptable for now, but there must be no letting up in our attention to the ways to be followed for the long run: improve education, foster research, and encourage primary care.

During the Progressive Era our parents and grandparents enjoyed the healthy optimistic faith that modern medical science would one day provide all the answers to the problems of disease and disability. That was a good outlook to have, and most of the evidence suggested that it was well founded. We have only to look at the graphs for tuberculosis, pneumonia, poliomyelitis, rheumatic fever, infant and maternal mortality, heart disease, cancer, and life expectancy during the fifty years since the report of 1932. There is much yet to do, but no reason to believe that the success of the last 50 years cannot be repeated in the next 50. It will require money: maybe another percent or two of our national health care bill will need to go to research and development instead of to the shareholders in the for-profit hospital and nursing home chains. More research is essential if there are to be any long-term reductions in the cost of disease, disability, and premature death.

> "According to the Committee's studies the real needs of the people call for three to five times as many well-trained general practitioners as specialists, and most schools, therefore, should concentrate their energies on producing well-qualified general practitioners." [4]

It was not until 35 years later, after the Millis and Willard Reports in 1966, that the matter of educating young men and women for careers in primary care came to be taken seriously by more than a few medical schools. The efforts to encourage students to choose general medicine, general pediatrics, and family medicine have been partly successful, but the movement may be in danger of losing momentum as a result of some of the measures being taken to control medical care costs. Narrow specialization may seem to be a more secure choice than family medicine for an uncertain future, especially one dominated by medical corporations and DRG's.

If that is so, it is unfortunate indeed. Only better medical care, made possible by the work of biomedical research, and more personal medical care provided by primary care physicians will in the long run hold down the costs of the burden of sickness and disability. Only then would the best be eventually the least expensive.

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ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington, CT.

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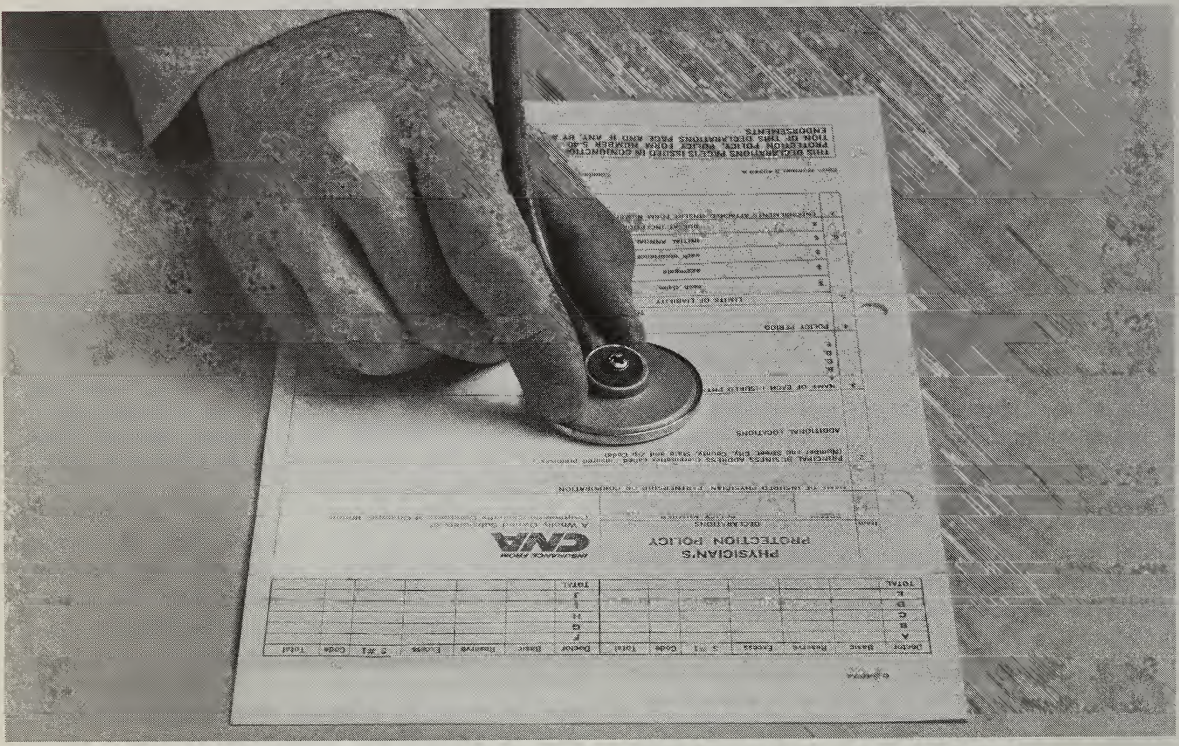

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Deciding for the Incompetent Patient: A Reasonable Role for the Law

JOSEPH M. HEALEY, J.D.

Concern about the appropriate role of the law in treatment decisions for the incompetent patient has stimulated consideration of various models of legal intervention. Most of the attention has been focussed upon judicial mechanisms to assure that incompetence has been properly declared, that an acceptable surrogate decision maker has been identified, and that decisions are made consistent with appropriate standards. The underlying issue is the degree of legal involvement at each stage of the decision process. There are theoretical and practical limitations to direct judicial participation in every stage of every decision. Yet, there are legitimate misgivings about the dangers of an unregulated or largely unregulated process. A recent journal article[1] by Robert Veatch, Professor of Medical Ethics at Georgetown University, presents a thorough analysis of this area of concern and recommends a direction for further policy development. His article will provide a good focal point for continuing examination of issues discussed in my previous two columns.

The Veatch article begins with a review of the legal and ethical principles governing refusal of treatment. He emphasizes that two primary ethical justifications have been traditionally accepted. An adult person of sound mind may refuse treatment that is useless or treatment that imposes a grave burden. He agrees that the incompetent patient should have the same rights with respect to refusal of treatment as a competent patient and that important distinctions between types of incompetent patients and also between types of decision makers for incompetent patients should be recognized. Veatch divides incompetent patients into two groups: those with known views which should be the basis of decisions made in their behalf and those without known views whose "best interests" should be the basis of decisions made in their behalf. Decision makers are also divided into two groups: Those who are "bonded" to the patient by family ties or by the prior wish of the patient and those who are non-bonded, such as court appointed guardians without prior knowledge of the patient. These distinctions are developed at great length by Veatch and are the cornerstone of his view of the appropriate degree of legal involvement. He argues that those patients who have previously expressed wishes about treatment dicisions should have those wishes respected. Those whose wishes are not known should have their decisions made by a "bonded" decision maker, when possible, or by a non-bonded decision maker when necessary. What then should be the role of the court in this process?

Veatch suggests three basic guidelines for legal involvement. First, the court should decide whether the patient is competent when the competency of the patient is in dispute. Second, if it is concluded, that the patient is not competent, the court should carefully monitor the selection and function of a bonded guardian who would assume the role of primary decision maker, supported and advised by the physician, other health providers and other trusted advisiors. Third, in those cases in which the patient is incompetent and there are no bonded guardians available, the court should exercise a supervisory role to assure that the decisions are made consistent with the best interests of the patient. If a bonded guardian is available, the court could intervene to select one family member from among several or to replace a bonded guardian who is not serving responsibly. The court might also intervene to review of a bonded guardian's decision for propiety. If a bonded guardian is not available, then the court should intervene to assure that the patient's interests are being served through the proper selection of a nonbonded guardian and through proper review of treatment choices. One interesting aspect of Veatch's framework involves the justification for permitting the bonded guardian greater discretion than the non-bonded guardian in cases where the wishes of the patient are unknown. He concludes that bonded guardians should be granted broader discretion because of their special relationship to the patient. He further argues that court review of the identification of bonded guardians should not be required in every case. He bases these conclusions in large part upon principles of autonomy and the rights of the family unit of which the patient is a member. Discussion and analysis of these conclusions will continue in next month's column.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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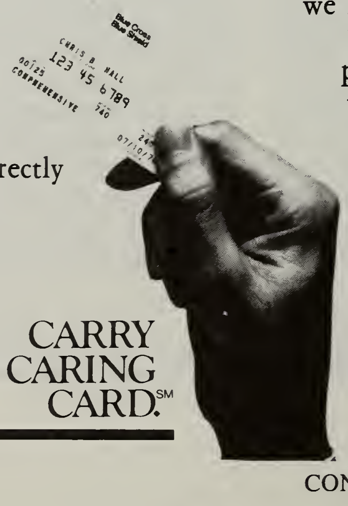

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Editorials

The Ethics Committee at Work

In December of 1982 the Medical Staff Executive Committee of the Manchester Memorial Hospital approved the institution of an Ethics Committee of the Medical Staff which was to assist in the interpretation or implementation of policies concerning life-prolonging treatments in those dilemmas of medical technology primarily concerning life-support systems. Originally this was to support the physician in the event that a patient was deemed to warrant a Do Not Resuscitate (DNR) formal order concerning the patient's care. It was felt that such a committee was needed in the increasing number of occasions produced by our ability to maintain viability in instances where quality of life, present and future, was abyssmal. Legal decisions had been promulgated to try to establish a status equivalent to death; legislation had been proposed to try to regulate the physician's duties with regard to the handicapped and critically ill newborn; and "living wills," "durable powers of attorney" and other instruments all added to the physician's uncertainty in already difficult situations. The Ethics Committee was to be available to assist and guide the Staff Physicians in facing these problems.

At Manchester Memorial the Ethics Committee was composed of seven members of the Medical Staff, an obstetrician, a pediatrician, a family practitioner, an oncologist, a cardiologist, a trauma surgeon, a psychiatrist, and an incorporator of the hospital who was an attorney, the hospital chaplain and a nurse who was a home-care coordinator. These committee members started out vigorously and prepared policies for the various problems which have been mentioned. One short year later, they were thrust into the midst of a case which developed national publicity and resulted in a landmark decision by the Connecticut Superior Court. This case involved a 42-year-old woman with terminal multiple sclerosis who was admitted to the hospital in respiratory arrest, resuscitated, and then placed on a respirator. She had essentially no quality of life, but was not brain-dead according to current standards, and the parents petitioned the court to have her life support withdrawn. The attending physician petitioned the aid of the Ethics Committee and the latter committee actively assisted both the physician and the hospital in helping to remove life support without fear of civil or criminal reprisals.

The Medical Ethics Committee indeed proved its worth. Every hospital should consider forming such a committee.

Merrill B. Rubinow, M.D., *Trustee*
Manchester Memorial Hospital

Colorectal Cancer and Flexible Sigmoidoscopy

Colorectal cancer is the second-leading cause of cancer deaths in the United States, with 126,000 new cases and over 58,000 deaths yearly. Yet public attention to this major health hazard has been small. Frank discussion of bowel habits and the importance of changes in stool color, consistency, size, and frequency are not conducive to media coverage.

Physicians, too, must accept some responsibility for this conspiracy of silence. A survey commissioned by the American Cancer Society found that while over half the U.S. population over 40 had annual health check-ups, fewer than one-third of these people were encouraged by their physicians to undergo proctosigmoidoscopy.

Reasons for patient and physician reluctance to undergo routine patient surveillance for colorectal cancer are varied. Some physicians are not convinced of the efficacy of the stool blood test. Patients may be unwilling to undergo proctosigmoidoscopy because of the discomfort associated with use of the rigid sigmoidoscope. Flexible sigmoidoscopy is a promising alternative, but few physicians have the flexible instrument and are properly trained in its use.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

In the next three years the American Cancer Society will be challenging the medical profession to intensify its efforts in colorectal cancer screening. The ACS hopes to increase by at least 25% the number of primary care physicians who regularly perform colorectal cancer checks. The following guidelines are recommended:

1. Men and women over 50 should have a stool blood test every year.
2. Men and women over 50 should have annual sigmoidoscopic examinations until two consecutive examinations are normal, and, thereafter, every three to five years.
3. Men and women over 40 should have a digital rectal examination every year.

The National Professional Education Committee of the American Cancer Society, in conjunction with the American Society of Gastrointestinal Endoscopy and the American Academy of Family Physicians has launched a physicians' training program to deal with the issue of flexible sigmoidoscopy. Compared with the rigid sigmoidoscope, the flexible instrument offers the possibility of a more complete evaluation of the rectosigmoid colon with less patient discomfort.

An effective screening procedure must be safe, sensitive, inexpensive and comfortable for the patient. Diagnostic flexible sigmoidoscopy would best achieve this goal if widely used by skilled primary care practitioners and provided at reasonable cost. Patients requiring endoscopic surgery or more extensive colonoscopic evaluation should be referred to gastroenterologists or surgeons appropriately trained and credentialed in these special procedures.

A well-publicized and widely-available program of digital examinations, stool blood tests and diagnostic flexible sigmoidoscopies, with radiographic or colonoscopic evaluation as indicated, will be an important step towards detection of colorectal cancers at earlier and more curable stages. A continued internecine debate between medical specialties based upon "turf" or economic self-interest will only further delay achievement of this worthy goal.

John C. Russell, M.D.,
Charles F. McKhann, M.D., and
Sherwin B. Nuland, M.D.

Professional Education Committee
Connecticut Division, Inc.
American Cancer Society

How About My Rights?

This column is dedicated to you young people who have exercised your rights prior to my treating you in the emergency room and operating rooms of the hospital. It is also directed at the young people whom I have yet to treat, but, who insist that "I've got my rights!"

I'm talking about your individual rights not to wear helmets while riding your motorcycles, your rights not to wear seat belts while racing your cars, your rights to "a few beers before hitting the road."

I've met you in the E.R. at all hours of the day and night—usually at night—late. Some of you I have known but could not recognize because of your injuries. Injuries that were the direct result of exercising your rights. Injuries that would not have occurred had you worn your helmet or your seat belt. Not pretty—and pretty painful.

Usually, by the time I arrive, some of the bravado has worn off as the pain sets in and the realization that you are really hurt takes hold.

"Will I be all right, Doc? Will I have bad scars? Am I hurt inside real bad, Doc? Am I going to die?"

Most of you don't die. Some of you did. The hardest night of my life was last September when I had to tell a mother—a lady very close to me—that her son was dead. And then I held her and watched the light go out of her eyes.

As I stand by your stretcher and assess your injuries and plan the repairs, I ask—"How come you weren't wearing your helmet?" (or seat belt). Briefly the bravado returns. "I've got my rights, Doc. Nobody can make me wear a helmet." Then I hear all the feeble excuses—the myths that have been passed from one misinformed youth to the next.

"I can't hear well with my helmet on." "I don't want to get trapped in the car by my seat belt."

The excuses, the reasons pour forth while I am wiping the blood from your mouth and trying to figure how to put your ear back on.

Then I get angry and I want to say to you what I am going to say now. I hope you read this over and over—and maybe just think about it—now that you are sober—now that you can look at your scars in the mirror. This is what I want to say.

"What about MY rights? What about my right to a night's sleep before a full day's work without being dragged into E.R. at 2 a.m. to patch up another maimed teen-ager?"

What about your parents' rights? Their rights to assume you are acting responsibly with your life, and the lives of those with you? What about the rights of all your friends and family who anguish when they see your pain—your needless pain?

Never mind your rights. LISTEN when we say "Wear your helmet! Wear your seat belt!", we are not imposing rules or rescinding your rights. We are saying: "We love you!"

—David Hochberg, M.D., Chief of Surgery, Day Kimball Hospital, Putnam, CT.

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FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511 Telephone 865-0587

Timothy B. Norbeck, *Executive Director*
Josephine P. Lindquist, *Associate Executive Director*

Raymond T. Sullivan, Jr.
Assistant Executive Director
Public Affairs

Robert J. Brunell
Assistant Executive Director
Scientific Activities

Richard J. Fiorentino
Coordinator
Special Services

COUNCIL MEETING

Thursday, September 6, 1984

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Ahrens, Alisberg, Bobruff, Canzonetti, Czarsty, Freedman, James, Kamens, McDonnell, Mendillo, Orphanos, Petrie, Ragusa, Sadowski, Scheer, Sullivan, Sweet, Villa, Waldron, Whalen and Zlotsky.

Also present: Dr. Fabro, Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Sullivan, Mr. Tomat (FCMA), Mr. Meister (NHCMA), Mr. Coffey (HCMA), and Mrs. Eslami (President, Auxiliary).

Absent were: Drs. Abbot, Ahamed, Beck, Bonner, Concannon, Dardick, Doctor, Friedberg, Kaess, Reyelt.

Reports From Physicians Serving on State and Federal Agencies

Dr. Kamens reported on his experiences in serving on the Task Force on Prospective Payment System for Hospitals to comply with Public Act 84-315. It was VOTED to distribute this report to the Council.

Mr. Fiorentino reviewed his staff report and drew particular attention to the special report on a project of the Business Coalition on Health entitled "Analysis of Patterns of Hospital Use With Small Areas." After considerable discussion it was VOTED to refer the matter to Committee on Hospitals for study and monitoring and report back to the Council.

Report of The President

Joseph S. Sadowski, M.D., reported on the following items:

Interview for CSMS Legislative Representative—President Sadowski reported on a recent meeting attended by Drs. Joseph S. Sadowski, Daniel W. Doctor, Jerome Bobruff, Isadore H. Friedberg and R. Leonard Kemler to interview prospective candidates to serve as the CSMS Legislative Representative. Six candidates were interviewed and the subcommittee agreed to employ the firm of Sullivan and LeShane for the 1985 legislative session. It was VOTED to retain the firm of Sullivan and LeShane for September, 1984-September, 1985.

Committee on Public Relations—Dr. Sadowski apprised the Council that John Callan, M.D., Chairman of the subject committee, had moved to Illinois. On the recommendation of the President, it was VOTED to appoint Michael Sharon, M.D., as the new Chairman of the Committee on Public Relations. It was further VOTED to change the name of the Public Relations Committee to the Public Affairs Committee.

Report of The Executive Director

Mr. Norbeck introduced to the Council Ray Sullivan who has assumed the responsibilities as the CSMS Assistant Executive Director for Public Affairs effective September 1, 1984.

Mr. Norbeck also reported on several items including the interviews for a legislative representative, CSMS staff involvement in the formation of CMIC, the AMA suit challenging the constitutionality of the Medicare Freeze embodied in the Deficit Reduction Act of 1984.

It was VOTED to have the Chairman of the Council appoint a small committee to work with CSMS legal counsel to prepare a statement on the Medicare Freeze to mail to the membership (NOTE: the committee consisted of Drs. Guy W. Van Syckle, Joseph C. Czarsty, Attorney Linda Randell and Tim Norbeck.) The following statement was sent to the membership:

> The Council of the Connecticut State Medical Society believes it is important for the physicians in Connecticut to be aware of certain provisions of the Deficit Reduction Act of 1984, passed by Congress this summer. The legislation made important—and we believe unfair—changes in the Medicare program.
>
> 1. The Act imposes a fifteen month freeze on payment rates to physicians for services to Medicare patients. Payment rates for services furnished from July 1984 through September 1985 can be no higher than the level set for the twelve months beginning July 1, 1983. As a practical matter, since rates have not increased in some time, payment rates are frozen at 1981-82 levels.
>
> 2. The Act imposes a penalty on physicians who, based on their practices and patients, wish to retain the ability to determine on a case-by-case basis whether to accept assignment. At the conclusion of the fifteen month rate freeze, if a physician was not a "participating" physician for the 12-month period beginning October 1, 1984, a further penalty is imposed: *no* increases in actual charges to Medicare patients will be recognized above charges billed for the 3-month

period ending June 30, 1984, in determining customary charges for the year period beginning October 1, 1985 and October 1, 1986. In other words, increases in actual charges will not be recognized until at least October 1, 1987 in determing the customary charge for a physician not "participating" as of October 1, 1984.

The American Medical Association has filed suit challenging the constitutionality of this legislation. The Council of CSMS supports this action and agrees with the AMA that the Act is unfair and discriminatory against physicians and their Medicare patients.

The Council believes that this statute will not correct the financial problems of the Medicare program. Moreover, the legislation may result in patients' inability to retain the physician of their choice because of that physician's inability or refusal, for financial reasons, to treat the Medicare patient at the fee levels dictated by the freeze. We believe that this legislation singles out the medical profession unfairly. In the face of rising fees in other areas (including physicians' suppliers), it is discriminatory to impose freezes and unfair restrictions on physicians. The penalty imposed on "non-participating" physicians disregards the individual character of practices and patients.

We have provided you this information to aid you in making your choice as to what to do. This is a matter for each physician to decide, based on his or her own practice and patients. Unless implementation of the statute is postponed by court action, this statute leaves physicians with two choices: (1) accept assignment for all Medicare patients treated (even those who can well afford to pay a physician's usual fee), or (2) determine on a case-by-case basis the charge to be billed to a Medicare patient.

It was VOTED to support the action of the AMA in filing suit challenging the constitutionality of the Deficit Reduction Act of 1984.

It was VOTED to accept Mr. Norbeck's report for information.

Report on The AMA Convention

A report on the actions taken at the June, 1984, AMA Convention in Chicago was distributed to Council members with the agenda. In addition, several members of the CSMS AMA delegation gave verbal reports.

It was reported that Robert McAfee, M.D., from Maine was elected to the AMA Board of Trustees.

Guy W. Van Syckle, M.D., was commended for being elected Chairman of the New England Delegation.

A Connecticut resolution on Bioethics Committees in Hospitals, was approved by the AMA House of Delegates, and it was VOTED to submit it to the CSMS House of Delegates for approval. The resolution follows:

RESOLVED: That the CSMS adopt the policy that each hospital form a Bioethics Committee with locally determined guidelines regarding composition, definition of roles, responsibility and authority; and be it further

RESOLVED: That the CSMS adopt the policy that such a committee be available for consultation in those medical illnesses presenting clinical problems complicated by bioethical issues and that a committee be voluntary, educational and advisory in nature so as not to interfere with the primary responsibiity of the physician to his/her patient.

Connecticut Seat Belt Coalition

Kenneth Dardick, M.D., could not attend the Council and asked William Whalen, M.D., to discuss the issue for him. Dr. Whalen mentioned that the coalition anticipated legal expenses from $1000-$2000 and would appreciate any help from the CSMS.

It was VOTED to approve of the concept of the development of the Connecticut Seat Belt Coalition as a non-profit organization.

It was also VOTED to refer the request of $1000-$2000 for legal expenses incurred by the coalition to the CSMS Fiscal Subcommittee.

Connecticut Peer Review Organization, Inc.

William A. Whalen, M.D., President of CPRO, commented on CPRO's request to the Society to recommend four individuals to serve on the CPRO's Board of Directors for the upcoming year. He provided background information relevant to CPRO's problems relating to CT's composition of the board in keeping the federal requirements. Dr. Whalen recommended, in addition to himself, Drs. Doctor, Canzonetti, and Eslami. It was VOTED to accept Dr. Whalen's recommendations for the CPRO Board of Directors.

Following this discussion Dr. Whalen provided the Council with a chronological update of CPRO's Request for Proposal (RFP) application to HCFA. CPRO's RFP has been re-submitted and CPRO should be informed of HCFA's decision shortly. If successful, CPRO's next action will be negotiations to determine costs to implement the program. However, business and insurance representatives have approached CPRO in regards to private review and CPRO plans to go ahead with private review and will be meeting with representatives of the Connecticut Hospital Association towards that objective.

Dr. Whalen also detailed CIGNA's Hospital Preadmission Certification Continuing Stay Review Program and the Care Corporation of Maryland, regarding appropriate admissions. He noted that the Peer Review Organization is the most appropriate organization set up to do the job.

Report on CMIC

Joseph S. Sadowski, M.D., President reported as follows:

A. Ad Hoc Committee to Interact with AHS Personnel— He discussed the activities of ad hoc committee of which he serves as chairman and mentioned that the committee had been meeting every Monday night for a period of four to five hours each time. Dr. Sadowski reported that the committee was functioning well and that important details having to do with the formation of the Connecticut Medical Insurance Company (CMIC) were being expedited. He expressed optimism that CMIC would be operational by October 1, 1984, and that at least 800 physicians would be participants during the first year.

B. Letter from Fairfield County Medical Association (FCMA)—President Sadowski mentioned that FCMA had recommended that CSMS terminate the contract with American Insurance Company (AIS) as of August 24, 1984, and that no further expenses be incurred in the implementation of the Connecticut Medical Insurance Company. He also pointed out that the insurance board (DOMAIN) of Hartford County Medical Association had recently voted to endorse CNA. After the two county actions, it had been agreed among Drs. Joseph S. Sadowski and Guy W. Van Syckle along with Tim Norbeck to poll the Ad Hoc Committee (Interacting with AHS Personnel) for a recommendation to the Council. The poll indicated strong support for the continued effort to implement CMIC and a Council poll confirmed that desire.

Dr. Sadowski also explained that the Office of the Insurance Commissioner required $1 million up front in order for CMIC to receive a Certificate of Authority to solicit surplus. The following three resolutions were adopted:

RESOLVED: That the Connecticut State Medical Society (the "Society") be and hereby is authorized to guaranty the repayment when due of a loan in the principal amount of $1,000,000.00 to be made by Medical Inter-Insurance Exchange of New Jersey ("Payee") to the Connecticut Medical Insurance Company ("CMIC") to enable CMIC to obtain a Certificate of Authority from the Insurance Commissioner of the State of Connecticut.

VOTE: 19 yes—3 No.

RESOLVED: That the Society be and hereby is authorized to guaranty payment by CMIC to Payee of the amount of the difference, if any, between interest accrued on the loan referred to in the foregoing resolution as of the date of payment and the amount of interest earned on the proceeds of such loan.

VOTE: 19 yes—0 No—1 Abstention

RESOLVED: That any appropriate officer of the Society is hereby authorized to execute and deliver any and all instruments and documents, and to take such other actions, as may be necessary or appropriate to carry out the foregoing resolutions.

VOTE: 19 Yes—0 No—0 Abstentions

The officers deemed appropriate were designated as the President, President-Elect, Vice-President and Chairman of the Council.

Mehdi S. Eslami, M.D., Chairman of the Committee on Professional Liability, commended Joseph S. Sadowski, M.D., members of the Ad Hoc Committee, and the CSMS staff for their efforts in making CMIC operational.

C. Letter from New London County Medical Association (NLCMA)—Dr. Sadowski commended the NLCMA for its endorsement of the Connecticut Medical Insurance Company (CMIC) and expressed appreciation to the New Haven County Medical Association (NHCMA) for its support of CMIC.

Alternative Medical Liability Act (H.R. 5400)

After discussion of HR 5400 and an offer by Ralph Pollock of the Business Coalition on Health (BCH) to attempt to develop tort reform legislation, it was VOTED to express CSMS interest in studying the option of contractual arbitration and in working with the BCH.

Proposal From
New London County Medical Association
RE: Medical Malpractice Reform

Jerome Bobruff, M.D., Chairman of the CSMS Committee on Legislation discussed a proposal submitted by George Sprecace, M.D. to adopt the option of contractual arbitration and to develop a mechanism of effective hospital and office peer review.

After discussion, it was VOTED to refer the matter of contractual arbitration and hospital and office peer review to the Committee on Professional Liability and the Committee on Legislation for their combined study, review and recommendation to the Semi-Annual meeting of the House of Delegates.

Joint Billing of Dues—Auxiliary and CSMS Dues

It was VOTED to include Auxiliary dues on the CSMS dues statement.

CSMS Bylaw Amendment

It had come to the attention of the Fiscal Subcommittee that the CSMS delinquency date for the payment of dues varied from the AMA and county associations. In order to bring uniformity, especially within the state, on the delinquency date, it was VOTED to approve the recommendation that the CSMS Bylaws be amended to change the delinquency date from August 1 to April 30 which will conform with the AMA and Hartford County, which has already made the change. Staff was requested to prepare the proper bylaw amendment for submission to the Semi-Annual Meeting of the House of Delegates in November 1984.

1985 Annual Meeting

It was VOTED to hold the 1985 Annual Meeting of the Society at the Park Plaza Hotel, New Haven on May 8, 9, 1985. The House of Delegates meeting will be held on May 8 and the scientific program will take place on May 9.

Report Re: House of Delegates Resolutions

The Committee on Hospitals was charged by the Council to follow up on resolutions passed by the House of

Delegates calling for CSMS to evaluate and report on the following aspects of physician credentialling:

1. The present methods for physician licensure in Connecticut.
2. The credentialling process used by Connecticut Hospitals.
3. The present method of communicating among the states the status of individuals practicing medicine with or without license, in or outside of the hospital setting.

Dr. Jerome K. Freedman, Chairman of the Committee on Hospitals, reported as follows on the above subjects:

1. Although there is some checking of the credentials of applicants for licensure, it was felt by the Committee on Hospitals that there should be more in depth investigation and that the Society should support adequate funding and staffing for the Bureau of Licensure to carry out this vital work.
2. Following a survey of the hospitals, the Committee reviewed the responses and found considerable variation in the credentialling process used by hospitals. Because of the disparate levels of investigation, the Committee recommended that a guideline checklist be recommended to hospital staffs that would include a specific and uniform list of elements of documentation and verification.
3. The Federation of State Medical Examining Boards maintains a computerized central repository of disciplinary actions and send monthly reports to its member Boards, key governmental agencies, and to the AMA Physician Masterfile. Although there is no legal mandate requiring Boards to report their disciplinary actions, voluntary reporting has improved dramatically in the past year, and reports have been received from every state and territorial jurisdiction. Utilization of the clearinghouse has also increased significantly, and direct-line computer access by member boards is now being contemplated. Medical Societies and hospital staffs can access to such data through AMA Masterfile.

It was VOTED to approve the recommendations and submit the report to the House of Delegates at the Semi-Annual Meeting in November.

N.B.: *The foregoing is a summary of the preceedings and actions of the Council on September 6, 1984. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

IN MEMORIAM

FAGAN, FRANCIS X., Cornell University Medical College, 1933. Dr. Fagan was an obstetrician and gynecologist in the Hartford County area since 1941. He was chairman of the department of Obstetrics and Gynecology at St. Francis Hospital and was president of its Medical Staff. Dr. Fagan was a member of the Hartford County Medical Association and the Connecticut State Medical Society, died September 9, 1984 at the age of 83.

LENCZ, ERWIN, University of Vienna, Austria, 1936. Dr. Erwin was a general practitioner in the New Haven County area from 1941 until his retirement several years ago. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died August 22, 1984 at the age of 72.

MORHARDT, CHARLES, New York Medical College, 1961. Dr. Morhardt was a general surgeon in the Hartford County area since 1968. He was a school surgeon for the American School for the Deaf and had served on the staff at Hartford Hospital. Dr. Morhardt was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died August 28, 1984 at the age of 47.

MORRILL, HAROLD F., Harvard University Medical School, 1925. Dr. Morrill was a surgeon in the New Haven County area since 1927. He was assistant city medical examiner for 35 years of his 46-year medical career and before his retirement, he was the attending staff surgeon at Waterbury Hospital. Dr. Morrill was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died July 29, 1984 at the age of 84.

MURPHY, THOMAS F., Jefferson Medical Center, 1933. Dr. Murphy was a pediatrician in the Hartford County area since 1934. He served on the staff of St. Francis Hospital for many years and was the chief of pediatrics for 13 years. In 1966, he founded the Cystic Fibrosis Clinic at St. Francis Hospital. Dr. Murphy was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died August 7, 1984 at the age of 76.

ROGOL, OSCAR, Dalhousie University Medical School, Halifax, Nova Scotia, 1932. Dr. Rogol was a internist in the New Haven County area since 1933. He was a senior member of the medical staff at Wicke Health Center and Wesley Heights Community, Shelton. Dr. Rogol was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died August 18, 1984 at the age of 80.

BOOK REVIEW

THE SECOND NINE MONTHS

By Judith M. Gansberg and Arthur P. Mostel, M.D. 220 pp., Tribeca Communications, Inc. New York. $12.95.

Every once in a while a book comes along which seems to answer an urgent need in a particular medical specialty. In this case, THE SECOND NINE MONTHS, by Gansberg and Mostel, fulfills a long overdue book for the Ob-Gyn practitioner.

This short, concise book of 220 pages is filled with facts that are broken into twelve chapter headings. The chapters run from the period beginning with the delivery of the woman and her reactions and responses to the hospital environment, nurses, and residents; and then goes on to describe in detail the reactions that women tend to keep to themselves but are expressed very clearly and succinctly in this book.

The chapter entitled "The Hospital" is perhaps one of the most interesting and informative pieces that contribute to the obstetrician's psychological knowledge of what is going on in their patient's mind prior, during, and immediately after delivery.

Physicians tend to isolate their area of work to that anatomical part that they are specialists in. The authors contribute information about the psychic makeup of women who have been interviewed and have described their reactions.

For example, the lochia, which continues for several weeks after delivery is a source of anxiety to mothers unless it is explained to them, very clearly, that this is a normal occurrence. Episiotomy is described, and some women find little discomfort, while others complain of severe discomfort for many weeks. Each individual's healing mechanism is different and the obstetrician can be reassuring to these women, and, therefore, the patients can deal with the problems in a much healthier environment.

The authors emphasize that motherhood consists of two components. The first is the emotional which is usually more difficult to deal with than the second which is physical. Reassurance and explanation usually deals with the physical but the emotional components which play a heavy role in many mothers frequently are the source of their attitude in handling of the postpartum stage.

This chapter entitled "In the Hospital" is one of the most interesting because it described not only the mother's relationship to the hospital staff but the beginning of a relationship to the first time she holds and feeds the infant, her responses to nursing, her response to the father and the frequent depressions that many women experience following delivery.

The next facet is the introduction of the pediatrician into the life of this mother. The authors suggest that the expectant mother should consider prenatal interviews with the pediatrician that is recommended to them or one that they choose. They state "the interview is valuable because it provides an introduction to the doctor so that the person doing that all-important examination of the newborn in reporting to the mother will not be a total stranger."

The next chapter entitled "The First Year" follows the new mother through various phases, with the authors recommending strongly that the first few days at home present problems that should be given some support either through mothers, mothers-in-law, fathers, or hired nurses. Mothers of first babies usually have the most difficult time because everything is entirely new to them as opposed to mothers who have had previous children.

Adjustments are constant during the first year in the mother's life and complaints of being bored, of feelings of being unattractive, are forced crises that can easily be dealt with using the suggestions outlined in the book.

The mothers who have had a history of being working women are analyzed, and very often the freedom that they experienced prior to delivery causes consternation in wondering if they will ever be able to return to work.

The fifth chapter deals with the relationship of the couple themselves, dealing with the husband's reaction to the infant, the problems of the husband feeling rejected, and the problems arising from difficulties with sexuality due to painful intercouse because of the episiotomy, or jealousy on the part of the husband for the time he had with his wife prior to birth is now being taken over by the infant. This kind of friction causes certain conflicts between the new father and the new mother and can be a problem in the relationship. Unless they learn how to communicate their mutual dissatisfaction, it often can lead to deterioration in their relationship.

Women are different in their adapting to a return to sexual relationships with their husband. A woman who feels she cannot wait for the six week period which is usually recommended, and finds that it is causing difficulty in her relationship to her husband, should speak to her obstetrician about intercourse at an earlier date.

The authors describe how mothers are tuned in to the sounds of their baby so that they cannot devote their full attention and time to their husbands, and are unable to achieve orgasm because their attention is directed to the infant rather than to the relationship that is ongoing.

One of the interesting facets of this chapter is the discovery by women that their sex drive is very often diminished after childbirth. Women expect to be exhilarated so that their sexual life is a strong requirement, instead they find themselves being tired, physically uncomfortable, and absorbed with the new infant that they cannot understand why they are rejecting their husbands in his sexual approaches.

This produces anxiety in the mothers who feel that the demands of the husband may be inappropriate, or that their husbands may not feel sympathetic to the new mother's problems.

Even Masters and Johnson are quoted stating that many women have a negligible interest in sex during the first three months and often describe dyspareunia due to the episiotomy.

The last part of this chapter deals with the need for a sexual therapist to help the couple overcome their difficulties experienced due to the introduction of the newborn infant. The authors also state that if there is good communication between the couple, usually these problems are easily resolved and require no assistance from other therapists.

Chapter Seven deals with a very important problem in our modern society and that is the working mother. It is difficult for the woman to give as much time to the infant without feeling guilt about returning to work. Industries today have the resources for these career women to bring the child if they are breast feeding, and they are cared for by specially trained nurses or helpers. At the same time, the husband has to assume certain responsibilities on his part in order to cooperate when she returns home. Husbands who do cooperate find a greater sense of bonding to the infant.

The chapter on postpartum depression is very well written. Postpartum depression is usually easily treated with the assistance of a psychiatrist. There are those women who prior to childbirth have had a history of depressive reactions, and following childbirth the exacerbation of their tendency towards depression is exaggerated. These women will usually require psychiatric assistance.

There is an excellent chapter called "The Single Mother" which is seen more frequently in our society today, our society is changing with such rapidity that frequently the medical profession, which is conservative by nature, has difficulty in dealing with these mothers, and often attempt to interject their own morality and judgment and bias. A word of warning is issued to those physicians who wish to impose their own judgments upon the new mother.

The remainder of the book goes through suggestions on helping the mother return her figure back to its prepartum condition. Illustrations are included of exercises. There is an excellent bibliography.

The book, THE SECOND NINE MONTHS, by Gansberg and Mostel is highly recommended to obstetricians, psychiatrists, pediatricians, nurses, and new mothers, who are interested in the development of the infant and the relationship of the infant to both mother and father.

JOSEPH D. WAXBERG, M.D.
Director, Sexual Therapy Clinic,
Department of Obstetrics/Gynecology
Stamford Hospital, Stamford, Ct. 06902

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

EMERGENCY MEDICINE

Connecticut, Southington: Full-time Emergency Department physician sought for Hartford area hospital. Desire primary care physician with Emergency Medicine experience. Contact H. Karl Dimlich, M.D., Director, Emergency Department, Bradley Memorial Hospital, Southington, CT 06489 (203) 621-3661.

A full-time position available in modern, well-equipped Emergency Room. 73 bed hospital in beautiful northwestern Connecticut. Contact Larry Ward, M.D., Director of Emergency Services, Winsted Memorial Hospital, 115 Spencer St., Winsted, CT 06098.

FAMILY PRACTICE

Family practitioner with larger, modern office in small community is looking for Associate leading to partnership. Write to: David L. Wasley, M.D., P.O. Box 27, Terryville, CT 06786.

Board eligible or certified family practitioner wanted for busy central CT office. Interested in eventual full partnership. Send CV to CSMS, FP/BK.

INSTITUTIONAL MEDICINE

HOSPICE PHYSICIAN. Position available to be part of the medical staff of the nation's first hospice. The Connecticut Hospice is a JCAH accredited hospital with a 44 bed inpatient facility and a hospice based home care program of 50 patients. Excellent opportunity for a physician interested in palliative care. Connecticut License required prior to employment. Board certification preferred. Full-time position but part-time applicants may be considered. Please C.V. to Mr. John M. Stober, Director of Human Resources, The Connecticut Hospice, Inc., 61 Burban Drive, Branford, CT 06405. An equal opportunity employer.

INTERNAL MEDICINE

Position available immediately in section of Internal Medicine in multispecialty group located in beautiful northwestern Connecticut. Salary guarantee leading to early partnership. Reply CSMS, IM/MJM.

MISCELLANEOUS

Physicians wanted for New Urgent Care Center in Branford, CT. The Coastline Medical Center, opening August 1, 1984, is equipped with Lab, X-Ray, Defib., etc. Pleasant surroundings. Malpractice insurance provided. Salary competitive. Full or part time. Send resume or phone: H. Ardolino, M.D., River Rd., Essex, CT 06426. (203) 481-0818.

OPHTHALMOLOGY

Full time associate, ultimately leading to take over practice. Write, CSMS, OPHTH/BEL.

OTOLARYNGOLOGY

Excellent private practice opportunity for board certified ENT sxpecialist in lovely northwestern Connecticut community of 12,000 only 45 minutes from Hartford. Service area population of approximately 35,000. Fully accredited 73 bed hospital with superior medical staff. Contact Mr. Paul E. Graff, President, Winsted Memorial Hospital, 115 Spencer St., Winsted, CT 06098.

PEDIATRICS

Pediatrician needed to join long established and very successful pediatric practice in Bristol, CT. 57-year-old soloist wishes to pursue additional postgraduate medical education. Quality practice leading to full partnership and eventual ownership. Write, CSMS, c/o PED/GJ.

PRACTICE FOR SALE

Established General Medical Practice available, including modern x-ray equipment. Also suitable for gastro-enterology, cardiology, and internal medicine. Write. "Medical Practice," P.O. Box 8162, Stamford, CT 06906.

Active practice of General Internal Medicine in Hartford suburb for sale to internist or family practitioner with balanced patient population, equipment and building. Write, CSMS, SALE/GB.

PSYCHIATRY

Assistant Medical Director, Alcoholism Ambulatory Service. Immediate opening for part time psychiatrist in fully JCAH Accredited comprehensive alcoholism program. Applicant should have interest in treating alcoholic patients and teaching medical students, residents and fellows, as well as have experience in group, family and individual treatment. Yale faculty appointment possible. Send resume to: Jerome M. Schnitt, M.D., Assistant Chief, Alcoholism Program, VA Medical Center, West Haven, CT 06516 or call 932-5711, ext. 345.

PHYSICIANS WISHING TO PRACTICE IN CONNECTICUT

ANESTHESIOLOGY

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Failure to Diagnose Secondary Syphilis

Two Case Reports

CARL S. WERNE, M.D. AND LOUIS GRUBIN, M.S.

ABSTRACT—The past year has witnessed a resurgence of patients with active syphilis in the Central Connecticut area served by the New Britain Sexually Transmitted Diseases (STD) Clinic. The two patients in this report demonstrate the concurrence of multiple venereal diseases and failure by the initial medical personnel evaluating the patients to consider syphilis in the differential diagnosis.

Case Reports

Case 1: The patient, a 19-year-old obese female, was referred to the Sexually Transmitted Diseases Clinic by a dermatologist who suspected syphilitic *Condylomata lata* and rash. She had been seen three weeks earlier by a gynecologist who noted genital lesions but performed neither genital cultures nor blood tests. The patient had noticed perineal pruritus of increasing severity over the past four weeks and abdominal pain for the previous five days. She did not complain of fever, dysuria, menstrual irregularities or vaginal discharge.

Pertinent findings on physical examination included a temperature of 99°F, a maculopapular rash on the abdomen and back, bilateral axillary and labial patches of *Condylomata lata,* right adnexal tenderness, and cervical motion tenderness. A stat serologic test for syphilis (Rapid Plasma Reagin) (RPR) was positive and a saline prep revealed multiple white blood cells. Pharyngeal, rectal, and endocervical cultures were performed for *Neisseria gonorrhoeae* and a vaginal culture was taken for *Trichomonas vaginalis.* A diagnosis of secondary syphilis was made and the patient was treated with benzathine penicillin G, 2.4 million units by intramuscular injection.

Because of a presumptive diagnosis of concurrent nonspecific vaginitis, she also was treated with ampicillin 500 mg. by mouth, four times daily for seven days. Tetracycline therapy was withheld pending pregnancy test results. The patient was evaluated by a nurse epidemiologist for contacts and was scheduled for a return appointment. Subsequent culture reports revealed *N. gonorrhoeae* present in the cervical and rectal specimens and T. vaginalis present in the vaginal culture; a serum VDRL (Venereal Disease Research Laboratory) slide flocculation test for syphilis was reactive at a titer of 1:128 and the fluorescent treponemal antibody absorption (FTA-ABS) test was positive. The patient was treated with Benemid 1 gm. by mouth and aqueous procaine penicillin G 4.8 million units by intramuscular injection for gonorrhea, and with Flagyl 2 gm. by mouth for trichomoniasis.

With therapy, the lesions of secondary syphilis resolved, only to reveal bilateral *Condylomata acuminata* present around the vaginal orifice. The patient was treated with tetracycline 500 mg. four times daily for seven days for possible chlamydia infection and was referred to a private physician for cryosurgery therapy for venereal warts.

Case 2: The patient, a 23-year-old white female Go-Go dancer, came to the New Britain General Hospital Emergency Room in June 1982 with a chief complaint of burning and itching of the vulva.

Physical examination revealed left inguinal adenopathy and two nontender ulcers on the right posterior labia majora. Laboratory workup included a VDRL and cultures for *N. gonorrhoeae* and genital herpes. She was treated with Vibromycin 100 mg. twice daily by mouth for suspected chancroid, counselled regarding return appointments and discharged. Subsequent laboratory results revealed a positive herpes simplex type 11 culture, and a reactive VDRL at a titer of 1:16. The fluorescent treponemal antibody absorption test was positive.

Despite attempts to contact the patient for follow-up evaluation, she was not seen until September 1982 when she returned to the Emergency Room for trauma related problems. She was treated with Erythromycin 500 mg. four times a day by mouth for 15 days, due to a claim of penicillin allergy. A repeat VDRL was reactive at a titer of 1:8.

The patient returned to the Emergency Room early in December 1982, intoxicated and complaining of a headache. Although the physical examination was unremarkable, a repeat VDRL was reactive at 1:16 dilutions. Because of her life style and history of non-compliance, she was persuaded to come into the hospital in January 1983. Pertinent physical findings at that time included bilateral cervical, inguinal, and axillary adenopathy, multiple painful genital lesions, patches of erythematous macules on trunk and moist papules around the mouth. A diagnosis of secondary syphilis was made after darkfield examinations of multiple skin lesions confirmed the presence of spirochetes resembling *Treponema pallidum.*

The patient was started on desensitization procedures revealing no true penicillin allergy. A cerebrospinal fluid VDRL was non-reactive while a serum VDRL was reactive at 1:32 dilutions. She was given benzathine penicillin G 2.4 million units by intramuscular injection and discharged with two scheduled appointments for repeated doses of benzathine penicillin.

Discussion

With the recent concerns over herpes, chlamydia, and acquired immune deficiency syndrome (AIDS), one of the oldest of all venereal diseases, syphilis, tends to be neglected in the differential diagnosis.

Over the past year, there has been a significant increase in patients with primary and secondary syphilis attending the New Britain Sexually Transmitted Diseases Clinic. The increase in patients with active syphilis parallels a national trend which has shown a 53% increase in reported cases of syphilis from 1977 to 1981.[1] Current statistics from the Centers of Disease Control indicate a 54% increase in syphilis in Connecticut for the first six months of 1983 when compared to the same period during 1982.[2]

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Syphilis has been known as the "great imitator" since its first appearance in Western society.[3] In each of the two case histories presented, syphilitic disease was not considered, delaying prompt diagnosis and treatment. This has become even more apparent in two subsequent cases. One male patient presented with a complaint of right-sided hernia, and was found to have a penile chancre with right-sided inguinal adenopathy. The second, a male homosexual prostitute, was treated on several occasions at a local emergency room for scabies due to a widespread and persistent maculopapular rash. However, several weeks later, a pre-employment serologic test for syphilis (VDRL) was reactive at a titer of 1:64, and FTA-ABS test was positive. This patient had been involved in hundreds of professional sexual encounters over the previous three months.

It is increasingly common to find multiple sexually transmitted diseases in the same patient.[4] We strongly emphasize that when one disease state is found, the physician should consider the presence of another. In addition, the multiple presentations of syphilis are not widely appreciated by many practitioners, and a review of clinical signs, diagnostic tests, and treatment protocols should be undertaken by the medical community in Connecticut. Public insistence on the pre-marital VDRL and re-emphasis on routine syphilis blood screening tests in all medical settings for sexually active patients should be organized.

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Pulmonary Metastases and Ovarian Cancer

V. KERR, M.D.

Introduction

Ovarian carcinoma is a recognized threat in women disproportional to its actual numbers. Although it is third in frequency among the gynecological cancers it accounts for the greatest number of fatalities, and is the fifth leading cause of cancer fatalities in women.[1,2] This is due in part to the difficulty of early detection and the high incidence of distant metastases during the course of the disease. From 36% to 75% of ovarian cancer patients already have distant metastatic disease by the time the diagnosis is made.[3,4] The lungs and pleura together constitute the most frequent site of clinically detectable distant metastatic involvement. [5-8] Screening for chest metastases may routinely be done through a series of chest radiographs. Despite this fact, little information is presented in the literature regarding the frequency, radiographic presentation, and accuracy of diagnosis of metastatic thoracic involvement for the different histologic types of ovarian cancer. The present study was undertaken to better characterize the frequency, duration, nature, and prognostic significance of pulmonary metastases for the different histologic types of ovarian cancer.

Materials and Methods

The clinical records of 397 patients with primary ovarian cancer were identified from the tumor registry at Yale-New Haven Hospital between the years 1966 and 1975. Of these, 373 were available for review. The records of 357 patients formed the material for this study. Patients were excluded if the records were incomplete, if a second primary had been diagnosed, or if surviving patients were lost to follow-up in under five years. For each patient the age at the time of diagnosis, race, parity, clinical stage at diagnosis, length of follow-up, tumor histology, therapy received, and ultimate or most recent clinical stage were recorded. Available autopsy protocols were included as part of the clinical record. Chest radiographs of all patients with clinically diagnosed chest metastases were reviewed with attention directed towards the sites and character of those metastases. Length of time to development of chest metastases and survival in months following detection of metastases were tabulated in these patients. The patients without previous clinical evidence of thoracic involvement but who had metastases to the

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V. KERR, M.D., Senior Medical Resident, Norwalk Hospital, Norwalk, CT.

chest diagnosed at autopsy were so classified and the chest radiographs for the three months preceding death were reviewed. In each case where possible an attempt was made to correlate the chest radiograph and clinical findings with autopsy or tissue sample results.

Of a total of 357 patients 159 developed some form of thoracic involvement during the course of the disease. Of these patients, 39.6% had histologic proof of metastatic involvement based on autopsy data or biopsy reports. Staging was according to the International Federation of Gynecologists and Obstetricians (FIGO) system without subdivisions in stage II. All stage II disease was classed simply as stage II because of the variable nature of the operative records.

Results

AGE. The patients ranged in age from one year to one-hundred three years old. The mean age of the entire group was 55.1 years. The patients with chest metastases had a mean age of 56.6 years at diagnosis compared to a mean age of 53.7 years for those without any evidence of chest metastases, a difference not statistically significant. Peak incidence occurred among the 45- to 54-year-olds, while the peak incidence for those patients with chest metastases occurred somewhat later in the 55 to 64 years age group. No chest matastases were found in the three youngest patients; however, in all the older age groups chest metastases were present in varying proportions (Figure 1). In general, younger patients had much better survival rates.

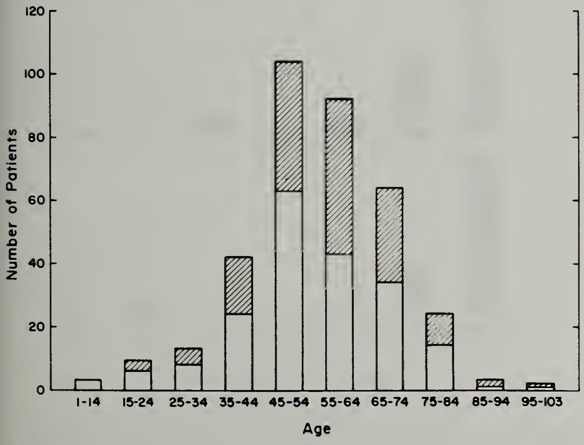

Figure 1
Age ranges of patients. Shaded areas represent patients with metastases.

RACE. The clinic population at Yale-New Haven Hospital is 81% white, nearly 17% black, and approximately 2% other ethnic groups. Among the ovarian cancer patients reviewed 91.1% were white and 3.9% were identified as black. Previous studies have shown significant racial differences in the incidence of ovarian cancer; however, few American authors have reported quite such a low percentage of blacks. The Connecticut Tumor Registry lists as black 2.4% of the ovarian cancer patients identified in the state during approximately the same interval as that of the current study (see Table 1).

Table 1

RACIAL FREQUENCIES OF OVARIAN CANCER PATIENTS

Source	*White*	*Black*	*Other Unknown*
CT Tumor Registry	95.8%	2.5%	1.7%
MD Anderson Inst.	86.3%	7.5%	6.2%
YNHH 1966-1975	96.1%	3.9%	–

Half of the blacks studied had some form of thoracic involvement, a proportion only slightly greater than the 44% of whites with pulmonary metastases. The difference is not statistically significant, however, partly because of the small number of blacks (N = 14) in the study.

The mean age of the black patients did not differ from that of the group. Over 90% of the tumors found in blacks were of epithelial origin. The five-year survival rate for blacks was 42.8%, somewhat higher than the 29% found for whites. The conclusions possible from such a small number of black patients are necessarily limited. Meaningful data on the age-incidence of different histologic types in blacks could not be compiled.

PARITY. Information on marital status was not uniformly available from the medical records; however, 22.4% of patients were nulliparous and another 18% had only one child. The obstetrical history was unknown in 16.5% of cases, while the remainder, 43.1%, had two or more live births.

SYMPTOMS. Both the cardinal and the associated symptoms were recorded for each patient if available (Table 2). The most frequently reported symptoms were increased abdominal girth, abdominal pain or pressure,

Table 2

FREQUENCY OF SYMPTOMS IN OVARIAN CANCER

Symptom	*Presenting Complaint*	*Frequency*
Increase in Girth	22.5%	33%
Abdominal Pain	21.6%	29%
Abdominal Pressure	7.3%	14%
Abnormal Vaginal Bleeding	7.3%	10%
Mass Detected by Patient	6.7%	9%
Gastrointestinal Complaints	3.0%	14%
Urinary Tract Complaints	2.5%	10%
Lethargy, Fatigue	2.2%	6%
Menstrual Irregularities	2.2%	5%
Back Pain	1.7%	5%
Weight Loss	1.4%	9%
Respiratory Complaints	1.4%	3%
Other	1.0%	12%
No Symptoms	10.1%	
Unknown	9.2%	

and abnormal vaginal bleeding. A significant proportion of patients, 10%, reported no symptoms at all. It is interesting to note that these patients did have a higher five-year survival rate than those patients reporting symptoms. This difference apparently was not due to any differences in the frequencies of histologic types or stage at diagnosis. Those patients with a longer duration of symptoms prior to diagnosis tended not to have any advantage for survival.

The incidence of vaginal bleeding was higher among patients with granulosa cell tumors and was reported in 50% of these patients. The number of patients with respiratory symptoms was remarkably low considering the number of patients with significant pulmonary invovlement. Also notable were the number of patients with no symptoms who were found to have extensive disease.

STAGE. As in previous series, most patients presented with advanced stages of ovarian cancer (see Table 3). Survival was found to be closely related to the stage at the time of diagnosis (Figure 2).

Table 3

STAGE

Stage	*Number of Patients*	*%*
I	69	19.3
II	50	14.0
III	180	50.4
IV	35	9.8
Unknown	23	6.5
Total	357	100

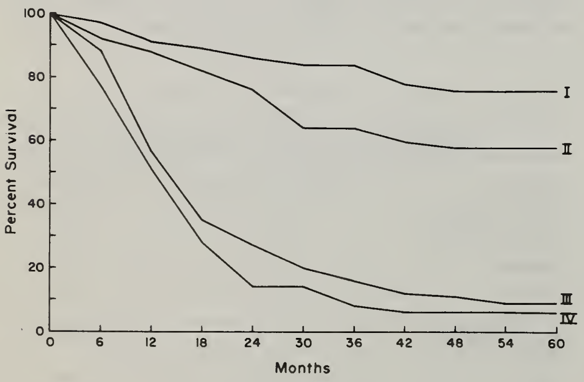

Figure 2
Survival according to stage.

SITE. Of the patients whose operative records and pathology reports indicated the site of origin nearly equal numbers of right-sided and left-sided lesions were found. The total number of unilateral tumors exceeded the number of bilateral tumors; however, in a significant number of cases no record of the site of origin was available (Table 4).

Table 4

SITE OF ORIGIN

Site	*Percent*
Right	20.4%
Left	20.2%
Bilateral	33.6%
Unknown	25.8%

Right-sided lesions produced a wider variety of pulmonary metastases (see Figure 3) and the incidence of pulmonary lesions was slightly higher among patients with right-sided tumors (Table 5). This small difference was not statistically significant. More striking was the proportion of patients with right-sided lesions who had Stage IV disease, nearly twice that of patients with left-sided lesions (Table 6). This difference was not reflected in the five-year survivals for the respective groups. Bilateral lesions had the worse prognosis for each stage.

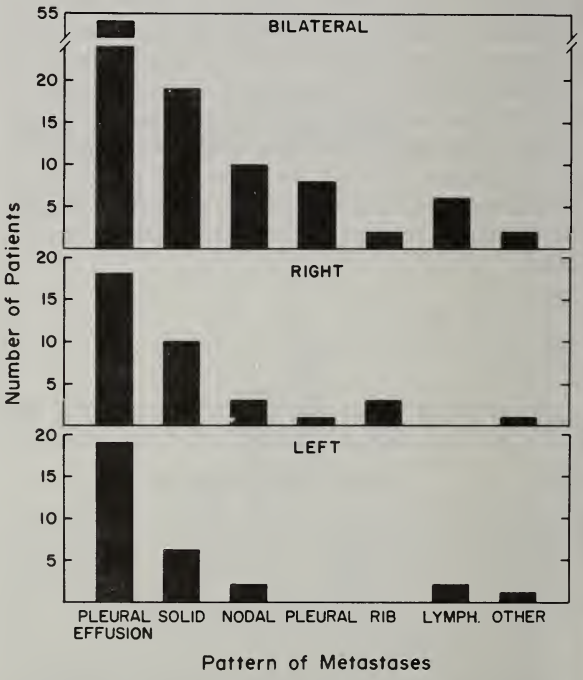

Figure 3
Incidence of metastatic types according to site. Some patients had more than one form of involvement.

Table 5

PRINCIPAL METASTATIC PULMONARY LESIONS BY SITE

	% Metastasis	*Type of Metastasis*					
Site		*Pl Eff*	*Solid*	*Pleur*	*Rib*	*Lymph*	*Other*
Right	38.5	63%	22%	4%	4%	0%	7.4%
Left	31.4	77	18	0	0	5	0
Bilateral	57.7	76	15	3	3	1.5	1.5

Table 6

STAGE ACCORDING TO SITE OF ORIGIN

Site	*I*	*II*	*Stage* *III*	*IV*	*Unknown*
Right	37.1%	17.1%	35.7%	10.0%	0
Left	35.7%	20.0%	38.6%	5.7%	0
Bilateral	7.8%	13.8%	70.0%	9.5%	0
Unknown	10.7%	9.5%	57.1%	15.5%	7.1%

HISTOLOGY. The most frequently occurring tumors were of epithelial origin, representing nearly 92% of the cases reviewed (see Table 7). A large number of epithelial tumors, 44.3% of all cases, were classified only as adenocarcinoma with no other specification. The serous cystadenocarcinomas amounted to 22.7% of the sample and mucinous cystadenocarcinomas were 12.3%. All other varieties of epithelial tumors comprised 12.6% of the sample. Among these were tumors characterized as undifferentiated or anaplastic carcinomas and these were included in the tabulations for epithelial tumors. The only tumors of sex cord origin found were granulosa cell tumors.

Table 7

INCIDENCE OF HISTOLOGIC TYPES

Histology	*# of Patients*	*%*
Epithelial	328	91.9
Serous	81	22.7
Mucinous	44	12.3
Endometriod	14	3.9
Clear Cell	8	2.2
Brenner	1	0.3
Mixed Epithelial	6	1.7
Undifferentiated	16	4.5
Adenocarcinoma	158	44.3
Granulosa Cell	8	2.2
Germ Cell Tumors	15	4.2
Dysgerminoma	1	0.3
Embryonal	3	0.8
Malignant Teratoma	9	2.5
Mixed	2	0.6
Other	6	1.7

The unspecified and the anaplastic carcinomas tended to occur more frequently among older patients; however, the difference in the mean age of patients with these histologic types was not significant. The mean ages for all the histologic groups are listed in Table 8. Most notable is the significant difference in the mean age of patients with germ cell tumors.

Table 8

MEAN AGE AND MEAN SURVIVAL BY HISTOLOGIC TYPE

Histology	*Mean Age (Yrs)*	*Mean Survival (Mos)*	*Age Range*
Serous	55.3	31.5	25-103
Mucinous	55.7	30.9	24-87
Endometriod	53.2	43.1	43-71
Clear Cell	51.0	29.7	17-62
Mixed	54.8	19.1	36-73
Anaplastic	57.6	19.8	35-79
Adenocarcinoma	57.4	25.0	29-97
Granulosa Cell	56.5	41.4	45-76
Embryonal	14.3	22.0	1-23
Teratoma	23.9	25.3	7-56
Mixed	20.0	39.0	16-24

PULMONARY METASTASES. One-hundred fifty-nine patients, or 44.5% of ovarian cancer patients, had some form of intrathoracic involvement. Forty-six of these patients had multiple pulmonary manisfestations, some diagnosed only at autopsy. Metastatic involvement included pleural effusions, parenchymal or solid metastases, lymphangitic metastatic disease, hilar or nodal metastases, solid pleural metastases, rib, pericardial, and pulmonary intravascular metastases. The radiographic patterns identified included effusions, adenopathy, nodular, lymphangitic and boney metastases.

The mean time from the diagnosis of ovarian cancer to the diagnosis of pulmonary metastases was 9.3 months with 33% of these patients presenting with pulmonary metastases at the time of diagnosis.

Five-year survivals were markedly lower for the patients with pulmonary metastases, as might be expected for any group of ovarian cancer patients with advanced disease. A comparison of the patients with pulmonary metastases and other Stage IV ovarian cancer patients revealed a lower five-year survival rate and a shorter mean survival time for the patients with pulmonary metastases.

Three cases of pulmonary metastases without parenchymal liver metastases at autopsy were found. In all these cases the mode of spread to the lung appeared to be non-hematogenous. A number of cases had pulmonary metastases detectable only at autopsy. The most frequently undiagnosed forms of pulmonary metastases were pleural, nodal, and lymphangitic. In each group more than half of the cases had these metastatic lesions diagnosed only at autopsy. None of the patients with lymphangitic metastases diagnosed by radiograph had an autopsy or tissue biopsy to confirm the diagnosis. Those patients with proven lymphatic metastases had radiographic evidence only of other forms of pulmonary involvement. The rate of false positive readings was minimal, however, with one case, involving a small parenchymal nodule, unsubstantiated at autopsy.

Table 9 lists the frequency of each type of pulmonary metastasis. Pleural effusions were the most frequent form occurring in 33% of ovarian cancer patients. Pleural effusions were present in nearly 75% of the patients with pulmonary metastases and in 54% of this group the pleural effusion was the only form of thoracic involvement. In 52 cases the pleural fluid was examined for evidence of malignant cytology and 73% of cases proved malignant.

Table 9

FREQUENCY OF METASTATIC TYPES

Type	*Principle Metastatic Lesion*	*Overall Frequency*
Pleural Effusion	72.3%	77.4%
Solid Parenchymal	17.6	28.3
Nodal	2.5	11.3
Solid Pleural	2.5	7.5
Lymphangitic	1.8	5.7
Rib	1.8	3.8
Pericardial	1.3	1.3

Mean survival time for the entire group after the diagnosis of pleural effusion was 9.2 months and the five-year survival rate was 2.6% for the group. The patients with non-malignant effusions had a significantly longer mean survival time from the time of diagnosis of the effusion than the patients with malignant effusions. No difference between these two groups was found for the mean time to diagnosis of pleural effusions, and although the five-year survival rate was slightly higher for the patients with non-malignant effusions, this difference was not statistically significant.

Parenchymal metastases were next in frequency occurring in 27.6% of the patients with thoracic metastases. The mean survival time following the diagnosis of parenchymal metastases was 10.6 months. The five-year survival rate for patients principally with solid parenchymal metastases was 14.8%. No survival advantage was found for those with solitary pulmonary metastases. The patients with parenchymal metastases as the only form of pulmonary involvement had a slightly higher five-year survival rate of 16.7% and a mean survival time after the diagnosis of metastases of 15 months. In 11 cases or 25% of the patients with parenchymal lung metastases some form of histologic confirmation of the tumor metastasis was obtained. The survival figures of these patients were similar to those of patients without histologic proof of the parenchymal metastases. In only one case did subsequent pathologic examination fail to confirm the radiologic diagnosis of parenchymal metastases. Four cases, or 9% of the group, had evidence of solid parenchymal metastases at autopsy without radiologic evidence of metastases. One additional case identified at autopsy was associated with a large non-malignant effusion. The best survival figures for patients with parenchymal lung metastases were in the group with early radiographic evidence of parenchymal metastases and subsequent regression or resolution of the metastases by radiograph after therapy. The five-year survival rate for these patients was 28.5%.

Other forms of metastatic involvement were found in 23.8% of the patients with pulmonary metastases. These metastases were most often found in association with other forms of pulmonary involvement with only two cases of nodal, three of pleural, two of rib, and one case of lymphatic metastases occurring as the sole form of thoracic involvement.

A total of 46 patients had multiple forms of pulmonary metastases. Of these 6.5% were alive five years after the diagnosis of ovarian cancer was made. The mean survival time following the diagnosis of pulmonary metastases in these patients was 8.3 months. Table 10 shows the relative frequencies of the different metastatic types in the patients with multiple metastases. No significant correlation between histologic type and the eventual development of multiple pulmonary metastases was found.

Table 10

FREQUENCY OF METASTATIC TYPES IN PATIENTS WITH MULTIPLE FORMS OF PULMONARY METASTASES

Type	*Frequency*
Pleural Effusion	73.9%
Solid Parenchymal	58.7
Nodal	26.1
Lymphangitic	17.4
Solid Pleural	17.4
Rib	8.7

Discussion

The sample population studied compares well with those of previous studies. The mean age of the patients in the current study, 55.1 years, is similar to figures reported by other authors. The racial composition of the group was slightly different from that of the ovarian cancer patients listed with the Connecticut Tumor Registry. Considering the racial composition of the area served by Yale-New Haven Hospital, the Connecticut Tumor Registry figure of 2.4% blacks is compatible with the 3.9% blacks found in the current study. A more striking feature is the disproportionately low incidence among blacks when compared to the percentage of black women in the clinic population at Yale-New Haven Hospital. This finding is consistent with the most recent results from the M.D. Anderson Hospital study and other series.[9] The distribution of patients according to histologic type and stage was similar to the figures reported by Smith and Day.[10,11]

The site of origin of ovarian tumors is seldom mentioned in previous studies. No relationship between site of origin and five-year survival rates was found. However, patients with right-sided ovarian malignancies had Stage IV disease twice as frequently as patients with left-sided lesions. This difference was just below the level of statistical significance ($P = 0.08$) and closely paralleled the result reported by Meleka.[12] Taken together the results of both studies suggest that right-sided lesions produce advanced disease more rapidly or more frequently than left-sided lesions. This finding can be explained by the differences in circulation of peritoneal fluid[13] and the anatomic differences in the environment of each ovary, including venous and lymphatic drainage.[12,14] Coincidentally, right-sided tumors also produced pulmonary metastases more frequently, although this difference was not so striking.

A comparison of the current findings on pulmonary metastases in ovarian cancer with those of previous studies is difficult because so few of them address this issue specifically.

Autopsy series from the Western Hemisphere show the rate of pulmonary metastases to vary from 1% to 34% in different series.[4,8,15-18] The rate of pulmonary involvement reported from M.D. Anderson Hospital was 21.3% with 7.5% having solid pulmonary metastases.[19] In the present study 44.5% had some form of pulmonary involvement. This rate may be slightly elevated because patients lacking chest radiographs were excluded. The effect of these patients on the overall rate of metastases would be small even if all of the excluded patients were found to be free from pulmonary metastases. In addition, the rate is probably lowered somewhat because the patients without overt evidence of metastases understandably had a lower rate of autopsy and pulmonary cytological studies, both of which might have revealed further undetected pulmonary metastases. The determined rate of metastases, then, is certainly a close approximation of the true rate of thoracic involvement for the group reviewed. One Japanese series found an even higher rate of pulmonary metastases with 67% of the ovarian cancer patients having some form of pulmonary involvement at autopsy.[20] No information about the type of pulmonary involvement was reported, however, limiting the usefulness of the study. Compared to other gynecologic malignancies, the rate of thoracic metastases in ovarian cancer is high. Sostman and Matthay found 20% of the patients with cervical adenocarcinoma and 4% of the patients with cervical squamous cell carcinoma had pulmonary involvement.[21] D'Orsi et al, found rates of pulmonary metastasis from 1.7% to 5.7% for various cervical carcinomas, and from 3.2% to 4.7% for endometrial carcinomas.

The rate of false positive radiographs was very low. Less than 1% of the cases with pulmonary involvement suggested initially by chest x-ray failed subsequently to have the diagnosis confirmed by other diagnostic measures. The rate of undetected metastases was somewhat higher, 13.8% of the patients in the group with pulmonary metastases had some form of radiographically undetectable metastases documented by other means. A number of these patients, nearly 45%, had concurrently other forms of pulmonary involvement which were detected on chest x-ray. The number of patients with pulmonary metastases who would not have been staged accurately if evaluated solely by chest x-ray was small, accounting for 7.5% of the group. This indicates that the chest x-ray is both a sensitive and accurate tool in identifying most forms of pulmonary involvement.

No cases of a second primary originating in or metastasizing to the lung were noted. Five cases were excluded from the review group, however, because of the development of a second malignancy. This represents about 1% of the cases identified by the tumor registry for the interval studied. Other authors have shown a significant increase in the incidence of breast, colon, and endometrial cancers among ovarian cancer patients.[22-24] Second primaries in the lung developing concurrently in women with ovarian cancer have also been reported.[24,25] The low rate of second primaries in the current study may be partly explained by the limited duration of follow-up and possibly by some exclusion from the ovarian cancer registry of patients developing a fatal second malignancy. Certainly the associations mentioned above have been reported frequently enough in long-term studies to expect commensurate rates in the current population if followed for more than five years.

The histologic type seemed to have little effect on the type or frequency of pulmonary metastases with two exceptions. Serous carcinomas produced malignant effusions more frequently than the mucinous carcinomas. This may be related to differences in the histogenetic qualities of the two types of epithelial tumors since serous tumors also undergo malignant degeneration more frequently than mucinous tumors. Patients with germ cell tumors had a markedly lower rate of pulmonary metastases. Only 20% of this group had metastases to the lung, and many of these proved to be of limited extent or clinically undetectable. This finding is consistent with the better survival rates for these tumors reported by some authors.[26,27]

A significant number of women with ovarian cancer presented with chest metastases evident at the time of diagnosis. A total of 14.8% of the patients with ovarian carcinoma, or 33% of the patients with pulmonary metastases had evidence of these at the time of diagnosis. This is not a surprising statistic since many women present with advanced stages of disease. That so many women have chest involvement when they first present to a physician simply underscores the importance of obtaining a chest x-ray when the diagnosis is strongly sususpected.

Pulmonary metastases can occur without any evidence of other distant metastatic disease. The frequency of this occurrence is not reported in any of the autopsy series reviewed.[6-9,17,28] In the current study three cases with clinically detectable pulmonary metastases had no evidence of liver parenchymal metastases or other Stage IV disease on autopsy except in the lung. This suggests that pulmonary metastases occur as the sole form of distant metastatic spread, although infrequently. In no case were pulmonary metastases present without evidence of intra-abdominal or peritoneal metastases.

Most of the patients ultimately having pulmonary metastases presented initially with either Stage III or Stage IV disease. No apparent survival advantage was found for those patients who presented with earlier stages of ovarian cancer and subsequently developed pulmonary metastases. It is clear that pulmonary metastases can occur regardless of the initial stage, including women rendered "cancer-free" after therapy. The same prognostic importance is attached to the presence of these metastases and the need for including chest x-rays regularly in the management of all ovarian cancer patients is again emphasized.

Summary

1. A total of 357 cases were reviewed and 44.5% of these had pulmonary involvement.
2. Pleural effusions were the most common form of pulmonary involvement with solid metastases second.
3. A large percentage of pleural effusions tested proved malignant.
4. Patients with pulmonary involvement had a lower survival rate than patients with other Stage IV disease.
5. Survival was poorest in patients with persistent pleural effusions.
6. Germ cell tumors had the lowest rate of metastases.
7. Serous carcinomas were more frequently associated with malignant effusions.
8. All forms of metastases can occur with any given tumor histology.
9. Nodal, pleural, and lymphangitic metastases were seldom detected radiographically but were frequently found with other types of metastases.
10. Right-sided lesions produced distant metastatic disease, including pulmonary involvement, more frequently among unilateral tumors.
11. Pulmonary metastases did not always occur as a result of progressive, linear spread from the primary site and may represent the only form of distant metastatic disease.
12. The chest radiograph was accurate in detecting pulmonary metastases greater than 90% of the time.

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Recurrent Respiratory Failure in Premenstrual Asthma

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Introduction

One third of asthmatic women experience worsening of their asthma in relation to menstruation.[1,2] Barkman recently described two sisters who died sudden asthmatic death during the premenstrual period but it had not been noted previously whether they had a history of monthly excerbation of symptoms.[3] We report a patient who had recurrent respiratory failure due to severe asthma just before or during menstruation which to our best knowledge has not been reported earlier.

Case Report

A 23-year-old woman had developed asthma after a pneumonia at the age of ten. Skin tests had revealed hypersensitivity to multiple allergens. She reached puberty at age twelve. Initially the asthma was controlled by intermittent bronchodilator use but when the patient was 16 years old she was hospitalized for asthma for the first time. She now noticed increased wheezing and shortness of breath just before and during her menses. She did not take medication, other than her asthma medicines, during the menstrual period and did not have a history of idiosyncratic reactions to aspirin.

For the next two years she had a number of severe attacks which required outpatient hospital treatment. From age 18 to 20 while she was taking oral contraceptives she was relatively symptom free. Then, over the next two and a half years there were 12 documented emergency room visits for asthma which resulted in hospital admission on ten separate occasions. All of these episodes were related to a premenstrual or menstrual period. A review of her records revealed that the admission dates followed a 30-day cycle. Several of the episodes were severe and she required mechanical ventilation on two occasions. Pulmonary function tests were normal between attacks. We saw the patient for the first time during her seventh hospitalization.

In view of the history of labile asthma with premenstrual worsening, the patient was instructed to begin taking prednisone immediately if an asthma attack was not relieved by inhaled metaproterenol, particularly if the attack occurred during the premenstrual period. A Wright mini peak-flow meter was given to her with the instructions to call if she noted a continuing fall in her peak flow. In spite of these precautions she was hospitalized with premenstrual asthma three times over the next six months. During that time oral contraceptives were tried without significant improvement. The patient then moved to her parents home in another town and was lost to follow up. When contacted a year an a half later she had been hospitalized recently in another hospital, requiring intubation for the third time for premenstrual asthma. She had moderately severe dysmenorrhea and premenstrual syndrome. Peak flow measurements did not reveal wide diurnal variations. During a total of five months of monitoring there was a marked decrease in peak flow during three premenstrual periods, two of which were followed by hospitalization for asthma. Steroid therapy had been given during the other two premenstrual periods.

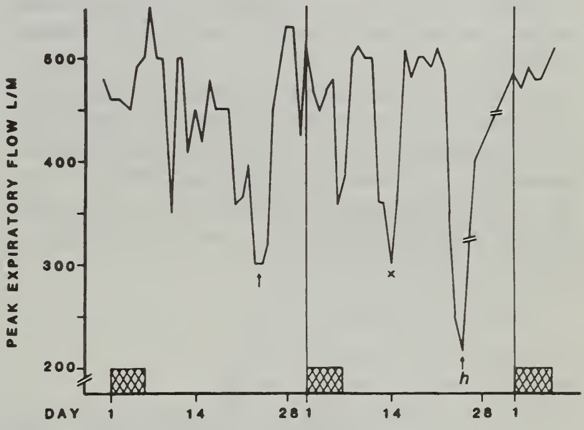

Figure 1

Daily peak expiratory flow measurements during two menstrual cycles. The peak expiratory flows reach a minimum during days 24 to 26 of both cycles (arrows). The patient was hospitalized (h) with acute asthma during the second premenstrual period. A decrease in peak expiratory flow is also seen during ovulation (x) of the second cycle and possibly also during ovulation of the first cycle.

Discussion

Patients who have wide diurnal swings in peak expiratory flow rate have been found to be at risk for sudden severe recurrence of asthma resulting in respiratory failure or even death.[4,5] The severity of the recurrence of asthma in relation to menstruation in our patient raises the question whether the presence of monthly variation in asthma symptoms identifies women with severe asthma who are at risk for respiratory failure or even sudden asthmatic death as reported by Barkman.[3] Such a hypothesis is supported by our experience that ag-

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gressive management including corticosteroids is often required to treat this premenstrual exacerbation of symptoms.

At present the mechanism of worsening of asthma in relation to menstruation is unknown. Rees[1] noted that women with premenstrual asthma had more severe premenstrual syndrome than asthmatic woman without a history of monthly exacerbations. Dalton[6] considers exacerbation of asthma as one of the features of the premenstrual syndrome. Other diseases known to worsen during the premenstrual period are migraine, epilepsy, glaucoma and supraventricular tachycardias, to name a few.[6]

It is interesting that the peak expiratory flow pattern of our patient followed the "B pattern" of the premenstrual syndrome, namely a shortlived worsening during ovulation followed by more severe worsening during the premenstrual period. This pattern of change of the peak expiratory flow (and symptoms) seems to follow variations in plasma levels of prostaglandin F2α which has been found to rise during ovulation and prior to menstruation in healthy women.[7] Both inhaled and intravenously-given prostaglandin F2α induces bronchoconstriction in normal subjects but more so in asthmatics.[8] The role of prostaglandins in premenstrual asthma has not been investigated so far and remains speculative.

The severity of our patient's symptoms seemed to vary from cycle to cycle similar to the monthly variations in the premenstrual syndrome.[6] Dalton[6] attributes the premenstrual syndrome to progesterone deficiency during the luteal phase and suggests that this progesterone deficiency and consequently the premenstrual syndrome is aggravated by oral contraceptives. However in a survey of 19 women with premenstrual asthma we have not found any consistent effect of oral contraceptives for the better or for the worse, which is similar to the findings of Hanley.[2]

Premenstrual asthma has received remarkably little attention in the literature; the publications on the subject can be counted on the fingers of both hands. This case report illustrates the potential severity of this monthly worsening of asthma. The overall health and social impact of premenstrual asthma may be more severe than suspected as it affects one-third of asthmatic women.

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Vision Training and Learning Disorders

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ABSTRACT—A possible role for orthoptics in the therapy of learning disabilities is described with an illustrative case presentation.

Learning-disabled children are being denied a potential remedial resource to assist them. This is because of a total abrogation of a therapeutic modality by professional organizations. Visual training and orthoptics have been successfully used[1-3] in the remediation of learning disabilities.

The American Academy of Ophthalmology and the American Association for Pediatric Ophthalmology issued a policy statement which denigrates the use of visual training completely.[4] One of the papers used as a reference for this statement[5] does note that both ophthalmologists and optometrists find higher rates of visual malfunctioning in groups of poor readers than in groups of good readers. The difference between these groups refers to whether the visual malfunction (erratic

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fixation, hesitation, regressions) is a result of or the cause of the reading difficulty. The statement also says that "such training frequently yields deleterious effects." Saunders[6] stated that "while vision programs are in themselves innocuous, they are frequently undertaken in lieu of appropriate medical or educational evaluation and treatment."

Case Report

R.A. was a two-and-a-half-year-old white female who has been followed from birth. She was the product of a normal pregnancy and delivery and her growth proceeded along the seventy-fifth percentile for height and the ninetieth percentile for weight. She had been in contact with other children her age in play groups since the age of eight months. Her development has been normal with the possible exception of some clumsiness in gross motor abilities. She was evaluated at an Early Intervention Program which found that there was a problem with distractibility and focusing of visual attention. Suggestions and outlines were given for stimulating gross and fine motor development. Six months later she was seen by an ophthalmologist who, though unable to objectively test her vision, determined that her problems were not eye-related. One month later she was seen by an optometrist who thought that marked fluctuation in her refractive state, short attention span, and difficulty in maintaining a steady, stable visual posture indicated that training lenses would help her. One month later it was noted by the mother that her clumsiness seemed to diminish by at least 75% and that she was very unhappy if she was denied her glasses. A follow-up evaluation at the Early Intervention Program showed a dramatic change in her ability to focus and to attend the task she was given and that she needed further work with her motor functioning.

Discussion

Solan[3] stated that 88% of learning disabled children, ages 6-13, had difficulty in accommodative facility (focusing ability). "The vision specialist can improve the learning disabled child's ability to sustain effort comfortably in reading and study type activity." Kauffman[7] speaks of visual near point dysfunction which can produce physiologically measurable changes in pulse rate and blood pressure as a result of this stress. Certain convex lenses can reverse these changes. This is called an avoidance response and may be one of the etiological factors involved in learning disability. Continued near point stress can lead to fidgeting and decreased attention span and behavior disorders.

Visual stress can occur as a result of near point dysfunction making necessary utilization of an increased amount of energy to maintain the visual task at hand. This stress can cause a constriction of visual fields thereby limiting peripheral acquisition of knowledge. Kauffman[8] goes on to state that elimination of visual stress may remove one of the major sources of poor attention span and its associated frustration and anxiety. Dr. R. Wunderlich is quoted[9] as stating that a learning lens (+ lens) can allow children to continue at the near-centered visual task and provides satisfaction of the avoidance urge.

Visual acuity and other more obvious visual functions[10] do not correlate with learning ability. However, anything that interferes with the free unstressed flow of written information can impair efficiency. Binocular fusion problems can be a cause of such stress. The argument that reading occurs successfully on a one eye basis does not consider the unconscious stress produced by inadequate fusion. Focus ability (accommodation) problems frequently interfere with sustained reading due to stress and avoidance factors. Sustained meaningful reading is dependent upon an easy flow of information from the printed page.

Lahey et alii[11] studied fifth grade and third grade children and though he found no difference in measurable peripheral aspects of vision he did find that eye movements in learning disabled children were generally slower and less smooth that their grade controls. He found that the younger children had an increased discrepancy in eye movements than the older children, thereby postulating a potential developmental lag.

Much of the literature expounding the benefits of visual therapy and/or orthoptics is flawed by having most of the learning disabled children involved in individual studies receiving educational help for their disability as well as visual therapy. This is exemplified by the Winterhaven Perceptual Training Program in 1959-60. Recent studies have even cast doubt on the efficacy of perceptual training programs themselves.[14]

The literature which opposes the use of visual training and/or lenses bases much of its argument on the question as to whether or not this type of therapy has proven to be more efficacious than placebo therapy alone.[6] The results of an international seminar held in 1969[12] concluded that not enough evidence existed to prove that perceptual motor training can influence reading disability and that the belief that eye dominance can be at the root of learning disability is "naive, simplistic, and unsupported by scientific data." There is an extreme variability in test results on normal and dyslexic children examined by ophthalmologists and results of these tests are not reproducible from one examiner to another.

When exercises for vision training and perception are carried out and evaluated, ophthalmologists find that although children improve in their ability to re-perform tests, this improvement does not spread to reading ability "unless specific training has been given concurrently in the reading skills themselves."[12] Those children with measurable visuo-spatial problems at 5-6 years of age showed no more reading difficulties three years later than children with no identifiable problems.[13]

The problems brought out by the case history presented are indicative of the difficulties that the pediatrician has of advising the parents regarding the position of optometric care in the area of learning disabilities. Most pediatricians follow the advice of ophthalmologists who are quite negative concerning any possible value in orthoptics. Despite these attitudes, a great many children are being treated by optometrists with or without our knowledge.

More study and investigation should be undertaken to determine whether or not the inclusion of optometric expertise in the overall treatment plan of learning-disabled children would be in the best interests of these children.

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Important Advances in Clinical Medicine

Epitomes of Progress—Pathology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in pathology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers or scholars to stay abreast of these items of progress in pathology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Pathology of the California Medical Association and the summaries were prepared under its direction.

Assessing Fetal Lung Maturity

Obsteticians are frequently faced with the decision to prevent premature delivery in a case of pregnancy complicated by premature labor. To this end, tocolytic agents are used such as the β-mimetic group, which may produce severe maternal side effects not directly related to dose or length of administration. These decisions to inhibit delivery must balance the possibility of newborn pulmonary distress due to lung immaturity against the risks of maternal-fetal injury or death by the labor-inhibiting therapy. Because the neonatal outcome is so closely linked to prematurity and lung function, a knowledge of fetal lung maturity is of paramount importance.

It is well established that fetal pulmonary maturation is closely related to surfactant lining the alveoli. Without adequate surfactant, immature alveoli collapse when exposed to air, and diffuse atelectasis leads to a respiratory distress syndrome. With amniotic fluid being in continuity with the lungs, it is possible to sample amniotic fluid to measure the pulmonary surfactant. The major components of pulmonary surfactants are phospholipids, predominantly lecithin. Because the maturation process involves a change from predominant amounts of sphingomyelin (which is a poor surfactant) to predominant amounts of lecithin (a good surfactant), the ratio of lecithin to sphingomyelin (L:S ratio) is a useful predictor of fetal maturity. Determination of the L:S ratio has been used for more than a decade since its introduction by Gluck and is still considered the most reliable test for assessing fetal lung maturity. More recently Gluck has augmented this test by measuring the percentage of desaturated lecithin and estimating the quantity of another important phospholipid—phosphatidylglycerol. This complex of tests (L:S ratio, phosphatidylglycerol and percent saturation of lecithin) is done in many laboratories serving obstetric services and is known as a "fetal lung profile."

The reliability of the lecithin-sphingomyelin ratio may be compromised by a number of factors, such as contamination of amniotic fluid by blood, meconium or vaginal secretions. Several maternal diseases have been reported to affect L:S ratios such as diabetes mellitus, sickle cell disease, severe toxemia, primary placental diseases and premature rupture of the membranes. The site of amniocentesis (distance from the fetal mouth) has also been reported to affect the L:S ratio results.

Fetal lung profiles require a thin-layer chromatography procedure that needs considerable technologic skill and at least three hours to do—both drawbacks in the middle of the night. Therefore, recent developments have been directed toward simplicity and rapid performance.

A recent adaptation of the "foam test" has become available commercially. The Foam Stability Index (FSI, SmithKline Beckman Company, Brea, Calif) provides a cassette with seven tubes containing various amounts of alcohol, with one tube being a control. The test has the advantage of simplicity and rapidity; however, the results are discontinuous and semiquantitative.

A rapid immunologic semiquantitative agglutination test for determining the presence of phosphatidylglycerol has recently become available. This test can be rapidly run but again is semiquantitative. In the fetal lung profile, the phosphatidylglycerol determination is quite specific for detecting respiratory distress syndrome, but its sensitivity is relatively low.

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Clinical trials of an instrument measuring microviscosity by fluorescence polarization have produced encouraging results, but it is still too early to be sure of the full clinical usefulness of either microviscosimetry, foam stability index or immunologic phosphatidylglycerol. Until there is more validation of these tests, the L:S ratio supplemented by phosphatidylglycerol determination and percent saturation of lecithin will continue to be the reference methods for assessing fetal lung maturity.

Richard K. Wertz, M.D.

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Asbestosis

Asbestosis is an occupationally induced, fibrosing lung disease caused by inhalation of asbestos fibers. Industry is now controlling exposures to asbestos more rigidly than in the past. However, the long latency of 10 to 30 years before asbestosis becomes manifest and uncertainty about the adequacy of control measures mean that the disease will remain for some time. Epidemiologic studies indicate that asbestosis progresses more rapidly in persons who smoke cigarettes or have certain endogenous inflammatory factors (antinuclear factor and rheumatoid factor). Curiously, persons with asbestosis often have cutaneous anergy to tuberculin and other antigens with cell-mediated responses. Nevertheless, clinically significant asbestosis occurs less frequently than other asbestos-related diseases. Malignant mesothelioma and lung cancer are often associated with asbestosis. Their possible asbestos-related cause has stimulated interest in using the early occurrence of asbestosis to confirm suspected exposure to asbestos. Early asbestosis can be diagnosed by scanning iron-stained sections of inflation-fixed lung for clusters of asbestos bodies in areas of fibrosis.

Evidence from several disciplines suggests that fibrosis develops first in the peribronchiolar region. Results of pulmonary function tests indicate obstruction, thought to be in small airways; experimental work in animals shows an early fibrosis around bronchioles, and quantification of fibrosis postmortem in persons with heavy asbestos exposure shows bronchiolar fibrosis. The early fibrotic lesion has been clearly linked to asbestos through measurements of the asbestos fiber burden in the lung by electron optical techniques, including transmission electron microscopy, electron diffraction and x-ray spectroscopy. In cases of asbestosis, an increase in the long, thin amphibole fibers, amosite and crocidolite, is positively correlated with an increase in the degree of fibrosis, whereas an increase in chrysotile, the fiber type most often used in the United States, is not. Whether this is because less chrysotile is inhaled or because chrysotile is more rapidly cleared from the lung than amosite and crocidolite is not clear. Asbestos bodies, visible by light microscopy, are a poor marker of asbestos burden. Their numbers reflect the concentrations of amosite and crocidolite fibers to some degree, but not the concentration of chrysotile fibers, which are generally too short to become coated with the iron-protein coat.

Epidemiologic surveys suggest that exposure to asbestos is a risk factor for lung cancer if asbestosis is present. In this country, only 25% to 50% of cases of mesothelioma are considered asbestos-related, based on a history of exposure and the presence of asbestos bodies and fibrosis in histologic sections. Because exposure to asbestos is often forgotten and does not always result in asbestosis, quantification of asbestos fibers may in the future show an unsuspected exposure in a higher percentage of cases of mesothelioma.

Martha L. Warnock, M.D.

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Cervical Warts

Colposcopy has provided significant new information about cervical warts. It is now widely recognized that, in addition to the classic papillomatous form (condyloma acuminatum), there are three other forms of cervical condyloma: flat, the most common form; the slightly raised form with asperities, and condylomatous cervicovaginitis with myriads of asperities. The distinct histopathologic and cytopathologic features of cervical condylomas have been well recognized since 1956, with the discovery of the hollow epithelial cells, the so-called koilocytes.

In viral, electron-microscopic and immunoperoxidase studies the human papillomavirus has been present in all forms of cervical condyloma. This DNA virus has epithelial affinity, belongs to the family of papovaviruses and has seven subtypes, the most common being type 6.

While the morphologic characteristics of human papillomavirus infection have long been recognized, its frequent association with various forms of cervical dysplasia (cervical intraepithelial neoplasia) has been studied only recently. By immunoperoxidase techniques, the human papillomavirus antigen was detected in 60% to 70% of mild and moderate dysplastic lesions (cervical intraepithelial neoplasia types I and II) and in a lower percentage of the more severe dysplastic lesions that lead to carcinoma in situ. The striking association of papillomavirus-induced cellular changes with forms of dysplasia that lead to carcinoma in situ raises the question of the virus's role in causing cancer.

According to statistical surveys, the incidence of cervical condylomas almost doubled in the decade from 1970 to 1980. The epidemiology of these cases shows a pattern typical of venereal disease, and it is well documented that human papillomavirus infection develops in two thirds of those who have intercourse with a partner who has genital warts. The mean incubation period is three months. In one study, condylomas were found in 19% of cervical biopsy specimens, and some form of dysplasia was found in 43% of the specimens with condylomas. Condylomas were present in 30% of the 146 cases with dysplasia. The mean age of patients with only dysplasia was 31 years but it was 24 years for those with dysplasia and condyloma.

Data suggesting that papillomavirus-induced cervical lesions may lead to cancer are rapidly accumulating. In an editorial recently the importance of caution in interpreting these lesions was emphasized. The authors concluded that "women bearing the virus-associated lesions should receive the same clinical and colposcopic evaluation, treatment and follow-up as usually administered to women with conventional forms of cervical intraepithelial neoplasia until more data on the natural history of these lesions are obtained."

John J. Molnar, M.D.

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Tumor Markers

A major goal in the war on cancer is to advance the time that malignancy is first diagnosed so that effective treatment can be instituted earlier. Pathologists are aware of histologic "markers" of malignancy and note that the cellular order of cancer is less differentiated and more like fetal tissue than is the structure of normal adult tissue. It is not surprising that tumors also often produce fetal products including proteins, enzymes, hormones, serum components, cell surface glycoproteins or cytoplasmic constituents that are characteristic of less differentiated tissue. Measurement of the serum concentrations of these "oncodevelopmental" markers in selected instances has been useful for diagnosis, prognosis and determination of the effectiveness of therapy. Immune labeling of tissue sections is useful for determining the origin of certain cancer cells, and radiolabeled antibodies to tumor markers are used to locate tumors in vivo by radioimmunoscintigraphy. More recently, antibodies to tumor markers have been administered to patients for passive immunotherapy, and experimentally the effectiveness of this procedure is increased by coupling toxic molecules, such as the α-chain of ricin, to the antibody.

The first cancer marker was recognized by a British physician, McIntire, in 1846. This became known as Bence-Jones protein in honor of Dr. H. Bence-Jones, who noted the association of this protein with a bone disease then known as "mollities ossium" and now called multiple myeloma. More than 100 years later, this protein, which precipitates in the urine of affected patients when the urine is heated at acid pH, was identified as an immunoglobulin light chain. During the past 20 years, many other tumor markers have been identified, such as carcinoembryonic antigen,α-fetoprotein, pancreatic oncofetal antigen, prostate-specific antigen, melanoma antigens, glial fibrillary protein and other nerve cell products as well as excess or ectopic hormone production, production of enzymes or isozymes, keratin, cytoplasmic proteins and connective tissue components. In a limited number of cases, production of a biologically active molecule such as a hormone may result in symptoms ("paraendocrine syndrome") that may call attention to the possibility of production by a tumor.

At present, a number of new markers is being identified by monoclonal antibodies. The high specificity of this generation of reagents may permit much more precise diagnosis. In addition, monoclonal antibodies may open the door to more specific immune therapy by passive transfer. In anecdotal reports such an approach has shown positive results in selected patients. Broad clinical trials are now under way.

The increasing availability of molecular probes for DNA or RNA sequences or rearrangements associated with cancer may ultimately provide new diagnostic approaches not now available. About 50% of tissues from hepatocellular carcinoma contain hepatitis B virus DNA, and several animal "oncogenes" have been identified in human cancers. It is possible that probes for such structures or for gene rearrangements may replace histologic examination as the major diagnostic tool for differentiating normal and cancerous tissue. For the foreseeable future, however, definitive cancer diagnosis depends on pathologic examination of a tissue specimen, and tumor markers remain useful adjuncts for tumor diagnosis.

Stewart Sell, M.D.

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Prognostic Features and the Management of Cutaneous Malignant Melanoma

During the past decade one of the major advances in the management of malignant melanoma has been the ability to distinguish two categories of patients: those unlikely to experience recurrence or spread (low-risk primary) and those with significant risk (high-risk primary).

The criteria of these two categories include both clinical and histologic factors. The most important histologic feature is tumor thickness measured in millimeters from the skin or ulcerated surface to the deepest area of invasion. Tumors less than 0.76 mm are of low risk and those greater than 1.5 mm are of high risk. Additional factors include the mitotic index, vascular invasion and microsatellites. Clinical factors must also be evaluated in assessing risk. Sex and site are major prognostic indicators—the prognosis for women is significantly better than for men for virtually all anatomic sites and the anatomic site as a prognostic factor varies from least risk (extremities) to greatest risk (head and neck), with the trunk posing an intermediate risk. The designations low-risk primary and high-risk primary are applicable only to the most common forms of cutaneous malignant melanoma—that is, superficial spreading and nodular types—which together constitute about 85% of cutaneous malignant melanomas. Unusual variants or unclassifiable primaries cannot presently be evaluated for risk of recurrence or spread, and microstage measurements with risk factors are used only for research purposes in such cases.

Current "standard" therapy for patients with malignant melanoma presenting in clinical stage I (primary excised, no evidence of metastasis) has been reexcision of the primary site to prevent local recurrence. Such patients have an overall five-year survival of about 80%, a better survival than with most forms of cancer. The prognosis for the low-risk-primary group is a better than 98% five-year survival. Patients with a low-risk primary can be treated with *conservative* reexcision (about a 1-cm radius) of the primary tumor site without risk of local recurrence. Patients with high-risk primaries have a prognosis directly related to their risk factors. Such patients may need a more extensive surgical procedure, including wider reexcision and perhaps elective lymph node dissection. The margins of surgical reexcisions are becoming more conservative, and elective node dissections are done less frequently, as findings from large patient populations continue to question the necessity or benefit of such procedures. Reexcisions requiring a graft for closure should be unnecessary in most cases and should not be undertaken as standard therapy for malignant melanoma per se.

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Sexually Transmitted Gastrointestinal Tract Diseases

Sexually transmitted gastrointestinal tract diseases in homosexual men encompass a number of protozoal, helminthic, viral, bacterial and chlamydial infections. Though several agents may be present simultaneously in one patient, not all of the infections may be symptomatic, but rather represent a carrier state. Most infections cause a nonspecific inflammatory reaction. The intestinal mucosa shows neutrophils in the lamina propria, increased numbers of lymphocytes or plasma cells and occasional crypt abscesses. There are some characteristic findings, however, that can be helpful in making a specific diagnosis. For example, *Giardia* and *Cryptosporidium* predominate in small bowel diseases. The latter organism on hematoxylin-eosin stain appears as a small, round, blue organism (3 to 7 microns) on the microvillous surface. These organisms stain blue with Giemsa. Periodic acid-Schiff and methenamine silver stains are not helpful because both react with mucins at the cell surface.

Viral inclusions should be diligently sought in colonic biopsy specimens, but are not always identified in culture-positive patients. Multinucleate cells and perivascular lymphocytic cuffing have been described with herpes simplex virus. Cytomegalovirus inclusions, nuclear and cytoplasmic types, can be seen in vascular endothelium, in cells in the lamina propria and in epithelium. Parasites such as *Entamoeba histolytica, Strongyloides, Trichuris* and even *Cryptosporidium* may be seen. If the biopsy specimen is from the rectum and if a prominent plasma cell infiltrate or multinucleate giant cells are seen, syphilis (plasma cells) or chlamydial infection (giant cells) should be looked for. These, as well as other bacteria—such as *Yersinia, Campylobacter, Neisseria, Salmonella* and *Shigella*—may simply cause nonspecific findings. Finally, hepatitis B can be sexually transmitted, and hepatitis A is probably transmitted by this route.

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Secondary Diseases in Immunosuppressed Patients

Normal function of the human immune system requires the interaction of multiple independent cell lines derived from a common pluripotent hematopoietic stem cell. The most important of these cell lines are the T and B lymphocytes and the phagocytes (macrophages and neutrophils). The B lymphocytes produce the specific antibodies required for humoral immunity, the T lymphocytes are primarily responsible for cell-mediated immunity and the macrophages process antigen in addition to their function as phagocytes.

Immune deficiencies may be congenital, iatrogenic or acquired. Patients with these disorders all show unusual susceptibility to infections and have an increased incidence of malignancy. The types of infections are, in a general way, predictive of the portion of the immune system involved. In patients with defects in humoral immunity, or neutropenia, recurrent infections with pyogenic bacteria tend to develop. Defects in cell-mediated immunity frequently result in disseminated viral, fungal and protozoan *(Pneumocystis carinii)* infections. Because of the complicated interactions of the immune system, patients with humoral immune defects may also have problems with viral infections and, conversely, overwhelming bacterial infections may develop in patients with cell-mediated immune deficits. The most common malignant conditions in which immune deficiency states develop are malignant lymphomas, both Hodgkin's and non-Hodgkin's. Acute leukemias also occur, and the incidence of Kaposi's sarcoma in the recently described acquired immune deficiency syndrome (AIDS) is striking. Other malignant conditions occur but are not increased in incidence above the normal population.

Congenital immunodeficiency states are rare disorders that generally present in childhood, whereas the iatrogenic forms are generally a result of aggressive therapy for malignancy or immunosuppression for transplantation. Until recently, clinically significant acquired immunodeficiency was uncommon; the recent outbreak of AIDS has changed that in many parts of the country.

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Cytomegalovirus Infections in Infants

Cytomegalic inclusion disease is an infection due to cytomegalovirus, a herpesvirus originally called salivary gland virus. This virus can produce a localized infection, affecting most commonly the gastrointestinal and respiratory tracts, or a generalized infection in which almost any organ may be involved. Histologically, a fairly typical eosinophilic intranuclear inclusion with a clear halo ("owl's eye") can be identified in affected tissues. Occasionally basophilic cytoplasmic granulations are also found.

Infants may acquire the disease in utero, during birth by contamination from the genital canal or by becoming exposed to the virus shortly after birth from sources such as breast milk, tears or other secretions. The infants who appear to be at greater risk are those born to mothers who have acquired a primary infection during gestation.

It is estimated that 0.5% to 2% of the neonates are excreting the virus and that, of these, major complications including central nervous system damage will eventually develop in a significant percentage (10% to 20%). Cytomegalovirus is the most common cause of viral-induced psychomotor retardation. Isolating infants known to be excreting the virus from schools or playgrounds is not practical since many nonidentified children are also excreting the virus.

The most specific and sensitive method for diagnosing a case of cytomegalovirus infection is isolating the virus from tissues, urine, saliva or other body fluids. Detection of IgG antibodies in an infant's blood specimen should be interpreted only in parallel with the mother's IgG antibodies because there is transplacental transfer of this type of antibodies from the mother to the fetus. IgM antibodies do not cross the placenta, but technical problems limit the diagnostic usefulness of routinely measuring their levels.

Vaccines, interferon and several drugs such as acyclovir have been evaluated for the prevention and treatment of cytomegalovirus infections. Although some encouraging results have been obtained, we do not yet have an effective method for controlling this disease.

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The Role of Coronary Collateral Arteries in Myocardial Ischemia

The questions whether well-developed coronary collateral arteries afford protection to an ischemic myocardium and whether various interventions such as exercise and pharmacologic agents promote collateral development have been studied in numerous experiments. The equivocal findings reflected the great variation in the number of naturally occurring collateral vessels in animals. Recent studies have been conducted in an animal model that has sparse, innate collaterals and a response to exercise stress similar to that seen in humans.

The effects of exercise on collateral development in myocardial ischemia were studied in pigs subjected to critical coronary artery stenosis and then given exercise training. After five months the exercise-trained animals had a greater increase in coronary collateral flow and smaller infarct sizes than their matched sedentary controls. These findings showed that development of the coronary collateral circulation and myocardial tissue salvage are enhanced by exercise training. Thus, exercise during an evolving infarct is effective as an augmentation to collateral growth but is not without risk. If embarked on, it should be conducted only under rigid medical supervision.

The effects of daily aspirin administration on collateral vessel development in cases of myocardial ischemia were studied in pigs subjected to gradual occlusion of a major coronary artery by an Ameroid constrictor. Coronary collateral blood flows were measured at rest and during exercise stress at three days and two months after coronary artery occlusion. The aspirin-treated animals had greater collateral blood flow during exercise stress (61% versus 45% of control; $P<.001$), smaller myocardial infarcts at autopsy (18% versus 32% of the myocardium at risk; $P<.001$) and more prominent collateral development on gross and histologic examinations.

The results of these studies indicate that in an animal with sparse innate coronary collateral vessels similar to those in humans, certain interventions can promote coronary collateral artery development and potentially protect ischemic myocardium by salvaging tissue in the jeopardized zone and reducing infarct size.

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The Flow Cytometer in the Clinical Laboratory

Flow cytometry involves passing a beam of laser light through a stream of cells and then analyzing the scattered light in relation to the number of cells stained by one or more fluorescent probes. This technique has been used for at least ten years in research laboratories to separate out specific cell populations and to analyze cells and cell populations with respect to surface antibody staining or DNA staining or both.

There are significant advantages to the use of the flow cytometer. Fluorescence microscopy seldom allows for the quantitative measurement of the staining properties of each individual cell, and becomes a very laborious process if more than a few hundred cells are to be analyzed. In addition, bulk measurements of collections of cells give average results for the overall population and do not really delineate possible subpopulations that often exist in lymphomas, for example. Flow cytometry, on the other hand, allows for the rapid quantitative measurement of thousands of cells and multiple properties of each. For example, DNA content and cell size can be used as criteria for the detection of abnormal populations of malignant cells. It has been shown that hyperdiploid cells can easily be distinguished from their normal counterparts by determining both the size and the DNA content of the cells. Braylan and colleagues have recently used the simultaneous measurement of DNA content and surface markers to define abnormal cell populations in malignant lymphomas. Because malignant cells are capable of changing during the course of a disease, it is important not to rely solely on one method of identification.

The clinical applications of the flow cytometer are generally restricted at present to the analyses of lymphoma and leukemia lymphocytes. Future application may involve a determination of κ- to λ-chain ratios. The amount of each chain on the surface of normal lymphocytes is about equal, whereas in malignant cells, a change in the ratio of κ- to λ-chains is observed. Other applications will involve the detection of autoantibodies in autoimmune hemolytic anemia, neutropenia and immune thrombocytopenia. Of these potential uses, the most developed at present is the detection of antibodies on platelets. Antiplatelet antibodies can be accurately measured in 1 ml of blood from a patient with a platelet count of 1,000 per μl or less. This determination cannot be done by any of the other techniques currently used because of the significantly larger numbers of platelets required.

The primary drawback of this system is the cost. Most flow cytometers currently used for clinical applications cost in excess of $100,000. For use in only a limited number of tests, most hospitals other than large centers for leukemia or lymphoma would have trouble justifying such a large capital expenditure. A problem specifically associated with such sophisticated equipment is that, in spite of attempts to simplify the mode of operation, a highly trained technician is needed to operate the machine because the likelihood of major breakdowns is quite high. In addition, the rate of cells passing through the machine cannot really be increased above 5,000 cells per second and this is relatively slow if one has to analyze a million cells to get reliable data. This is a serious drawback, and unless there is a basic change in technology, it will remain a major limiting factor.

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Current Trends in Drug Overdose

Drug availability, price and current fads are mainly responsible for changing trends in drug intoxication. In Los Angeles, phencyclidine hydrochloride (PCP) is widely available, relatively cheap and the most popular drug of abuse. The incidence of admissions to hospital for PCP intoxication is correspondingly high. Four PCP analogues with effects similar to PCP are available on the streets.

Cocaine use is rampant, and cases of severe cocaine poisoning are appearing sporadically. Some patients who die in status epilepticus have a ruptured package of cocaine in the bowel at autopsy.

Heroin, a perennial favorite, is presently abundant and down in price. Intravenous injection of heroin mixed with cocaine (a "speed ball") is an old combination regaining its popularity. A new fad is "smoking" heroin by heating it on a piece of aluminum foil and inhaling the vapors. As the drug volatilizes the particles "jump around" on the foil. This practice is called "chasing the dragon." The most popular narcotic appears to be codeine, usually taken in tablets containing either aspirin or acetaminophen. Acetaminophen intoxication remains a common problem.

Two drugs of the 1960s, glutethimide and LSD (lysergic acid diethylamide), have returned. Glutethimide is frequently ingested with acetaminophen and codeine. This combination, called a "Doriden load," is favored by persons with narcotic addiction as a substitute for heroin. Glutethimide overdoses are often life-threatening. LSD is impregnated on postage-stamp-size colored pictures printed sequentially on transparent plastic ("transfers") or white porous paper ("blotters"). Drug abusers lick these "papers," transfer the picture to their skin and experience LSD intoxication. LSD is also poured over small pieces of pasta for street sale.

The preferred hallucinogen for "new wave rockers" is MDA (methylenedioxyamphetamine), which may be sold as very small—about 4 by 6 mm—flat, rectangular transparent chips of crystallized material called "window panes."

The use of amphetamines, including "look-a-likes" containing caffeine or phenylpropanolamine, is increasing, especially that of crystalline methamphetamine called "crank."

Intoxication from various sleeping pills and benzodiazepines continues. The leading cause of intoxication is still ethanol alone or in combination with another drug.

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Fine-Needle Aspiration Biopsy of the Prostate Gland

Fine-needle aspiration has been used as a diagnostic tool since the beginning of this century. A mildly invasive technique, it has grown in popularity in the United States primarily on the basis of the ease and accuracy with which it can be used to obtain biopsy specimens to diagnose lesions in breast, superficial lymph nodes and thyroid. The prostate, however, is not so readily accessible and fine-needle aspiration of masses in this organ has not gained so ready an acceptance. After ten years' experience of doing this procedure on superficial lesions and the Karolinska Hospital in Stockholm, Dr. Sixten Franzen in 1960, constructed a needle guide that makes the prostate easy to reach through the rectum using a 22-gauge needle.

The use of fine-needle aspiration is indicated when there is a suspicious, palpable lesion in a prostate. If a patient presents with distant metastasis for which the prostate may have been the source of the primary lesion, random aspirations of the four quadrants of the gland can be done. Not infrequently, such quadrant biopsy specimens will confirm the diagnosis of prostatic carcinoma. Lesions of clinically apparent prostatitis should not be aspirated.

With the Franzen needle guide, specimens can be taken of even very small (about 0.5 cm) and superficial lesions with a high degree of accuracy. Specimens from several different areas of the prostate can be taken without significant hemorrhage or other side effects. Fine-needle aspiration of the prostate is an outpatient procedure and does not require anesthesia. Patient discomfort is minimal, and patients readily accept a repeat biopsy if it is required.

In contrast, a core biopsy specimen obtained with a cutting needle requires local or general anesthesia and is less accurate, especially for small and superficial lesions in the posterior portion of the prostate. The sections from a core biopsy show only a fraction of the cells present in the specimen. An aspirate specimen almost always shows more cells for study than does that from core biopsy. In general, cellular detail on cytologic preparations from fine-needle aspiration is superior to the paraffin-embedded sections of a core biopsy.

The main disadvantage of this procedure is that there is a shortage of physicians in this country experienced in the biopsy technique and in the interpretation of the resultant smears. Good results cannot be obtained through reading about the technique and then attempting to do it; fine-needle aspiration must be learned under supervision, and the smears should be examined to ensure adequacy of the material.

After acquiring sufficient skill in the technique, it is still necessary to do at least five to ten aspirations a week. This is about the same degree of experience necessary to maintain skills in microscopic interpretation. Optimal results are obtained if the same physician does the aspiration and interprets the slides.

When performed and interpreted by a trained physician, fine-needle aspiration of the prostate gland is a highly accurate, fast and minimally invasive biopsy technique. There is a great need in this country for training programs to instruct physicians in the techniques of fine-needle aspiration of the prostate gland and other organs. If trained physicians are unavailable, it is better to rely on traditional histologic techniques. During the transition period between the use of traditional (core) biopsy and the implementation of fine-needle aspiration techniques, it may be feasible to do both procedures until such time as enough experience with the aspiration technique has been gained.

Britt-Marie Ljung, M.D.

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Hepatitis-δ-Agent

The recent discovery of a new hepatitis agent called delta (δ) marks the most exciting milestone since the identification of hepatitis A and B viruses nearly two decades ago. The δ-agent is a defective RNA virus, thus a virus taxonomically distinct from the hepatitis B virus (HBV) but requiring helper functions supplied by HBV. Hence, δ-hepatitis can occur *only* in the presence of HBV, and has three clinically recognizable forms: concomitant acute B and acute δ-hepatitis, superinfection by the δ-agent in persons who are hepatitis B carriers and chronic δ-infection in a patient who has chronic hepatitis B.

Although simultaneous acute B and δ-infections can present as ordinary acute hepatitis, more often this dual infection results in a severe fulminant form.

δ-Superinfection in an HBV carrier may occasionally result in fulminant hepatitis but usually manifests itself as an acute icteric illness that is followed by chronic progressive liver disease. We now realize that the clinically evident, recurrent, hepatitis-like illness accompanied by jaundice that became more common during the late 1960s, which we all called chronic active hepatitis, was principally δ-modified chronic active hepatitis B. Data now show that, at least in the Los Angeles area, 82% of the drug users with chronic active hepatitis B also have δ-infection.

Our clinical colleagues have noticed a difference in the manifestations of chronic active hepatitis in drug users as compared with ostensibly the same disease in homosexual men or in Asian immigrants. Similarly, we have been impressed with the general difference in "aggressiveness" of the hepatic histologic patterns in drug users versus nonusers who have chronic active viral hepatitis B. A major difference has been the presence of δ-superinfection, common in the former and uncommon (but increasing!) in the latter. It is likely that the histologic features of chronic active viral hepatitis that most pathologists have learned actually represent the dual infection. Serologic tests for δ-antibodies and immunologic staining for δ-antigen in the liver tissues establish the clinical diagnosis.

The δ-infection is described as endemic in Italy and sporadic in worldwide distribution. A major outbreak of cases of severe hepatitis due to δ-infection recently reported from South America should alert physicians to test for δ-markers in any new outbreaks of severe hepatitis.

Sugantha Govindarajan, M.D.

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LD_6—A Biochemical Sign of Impending Death

An extra isoenzyme band of lactate dehydrogenase (LD) (EC 1.1.1.27) that is cathodic to LD_5 has been identified by several investigators. The underlying clinical condition is arteriosclerotic cardiovascular disease causing congestive heart failure with massive congestion of the major viscera. All of the patients had elevated total LD and creatine kinase (CK) levels. Serum enzyme electrophoresis showed that the LD_1level exceeded or was equal to $LD_2$and the CK-MB level was increased more than 5% as the acute myocardial infarcts evolved. As congestive heart failure became evident, a prominent amount of LD_5 became apparent, as did an LD_6 isoenzyme band cathodic to the LD_5 isoenzyme band. The ratio of blood urea nitrogen to creatinine was greater than 10:1 due to the progressive prerenal azotemia.

LD_6 is extremely stable at 56° C, 4° C and 25°C. It is not bound to an immunoglobulin and does not contain an H (myocardial) monomer but does contain an M (skeletal muscle) monomer. It may represent a post-translationally modified LD_5.

LD_6 is not an artifact and most likely should be metabolized and cleared by a healthy liver and kidney. It is present and is identified when there is ischemia of the liver and kidney with circulatory failure. The appearance of LD_6 portends a very poor prognosis—as does the presence of creatine kinase mitochondrial isoenzyme—and is a sign of impending death.

Paul Wolf, M.D.

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Heparin-Induced Thrombocytopenia and Thrombosis

Despite the fact that heparin is a powerful anticoagulant, it will infrequently induce thrombocytopenia and thromboembolic complications. Heparin-induced thrombocytopenia typically occurs about eight days after the institution of heparin therapy and is frequently followed by deep vein thrombosis, pulmonary embolism, arterial thromboembolic complications or a combination of these. Prior periods of heparin therapy will predispose some patients to the development of thrombocytopenia (less than 100,000 platelets per μl) as an anamnestic response within three to five days after reexposure. The episodes of arterial thrombosis or "white clot" syndrome frequently lead to infarction of end organs such as brain or heart or gangrene of an extremity. Although apparently ten times more likely to occur with bovine heparin than with porcine heparin, heparin-induced thrombocytopenia with thrombosis has occurred with both types. There does not appear to be a relationship to dosage, route or frequency of administration. The use of low-molecular-weight porcine heparin in this situation is promising but is still under study.

If the patient survives the thromboembolic complications, the platelet count usually returns to normal within two to four days after cessation of heparin therapy. Most patients who have been rechallenged with heparin after periods varying from a week to one year again manifested immediate thrombocytopenia.

In contrast to heparin-induced thrombocytopenia with thrombosis, there is a benign, mild depression of the platelet count that commonly occurs within two days after the institution of heparin therapy. Poorly understood, this type of heparin-induced thrombocytopenia is not mediated immunologically and requires no treatment. Although the reported incidence of both types of thrombocytopenia together reaches up to 30%, the incidence of clinically significant heparin-induced thrombocytopenia with thrombosis probably varies between 0.6% and 5%. No risk factors in an unexposed patient have yet been discovered.

Heparin-induced thrombocytopenia with thrombosis does not involve the action of thrombin but is mediated by an IgG antibody that reacts with heparin on the platelet membrane to activate complement. This reaction initiates thromboxane synthesis, which leads to platelet aggregation rather than platelet lysis. Aspirin will block this sequence of activation. This IgG antibody can be detected in most cases of heparin-induced thrombocytopenia with thrombosis by testing for platelet aggregation in the presence of heparin using an aggregometer. In aggregation studies of some affected patients, however, heparin has induced aggregation in vitro only when tested on specimens taken two to three days after cessation of heparin therapy.

The high rates of morbidity and not-infrequent mortality make prevention the treatment of choice. This is usually accomplished by monitoring the platelet count of every patient every two to three days during the first 15 days of heparin therapy. The onset of this condition should always be suspected when a patient shows increasing resistance to heparin, progressive thrombocytopenia, worsening thrombophlebitis despite heparin therapy or new thromboembolic complications during heparin therapy. If the laboratory and clinical findings indicate heparin-induced thrombocytopenia with thrombosis, heparin therapy should be terminated immediately, including any heparin used to maintain the patency of intravenous lines. Antiplatelet agents should be administered and vitamin K antagonists used if needed. A promising role for antiplatelet agents is suggested by a recently reported case of a dialysis patient who had heparin-induced thrombocytopenia with thrombosis who subsequently tolerated heparin well during dialysis by taking aspirin.

Jeffrey D. Cao, M.D.

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BEHIND THE FACE OF HYPERTENSION

New evidence for central control

Creatine Kinase Isoenzymes

Creatine kinase (CK) is an intracellular enzyme that exists as three dimeric isoenzymes; CK-MM, primarily from skeletal muscle; CK-MB, primarily from cardiac muscle, and CK-BB, primarily from brain and smooth muscle. Major interest has focused on developing methods of detecting and quantitating CK-MB in serum because of its diagnostic and prognostic implications in ischemic cardiovascular disease. Because both CK-MB and CK-BB are thermolabile, a laboratory must develop appropriate methods for procuring and storing specimens before analysis to ensure optimum isoenzyme activity. Electrophoresis is widely used to identify and quantitate CK isoenzymes and the only practical method for detecting abnormal variants of CK such as macrocreatine kinase (macro-CK). Ion-exchange chromatography and methods based on selective chemical activation of the MB isoenzyme have also been used. Isotopic and nonisotopic immunoassays are gaining in popularity because of increased sensitivity. It is imperative that each laboratory establish normal ranges and detection limits for the MB (and BB) isoenzyme(s) regardless of the method chosen.

CK-MM activity in serum increases following muscle work, trauma or ischemia. Myopathies also cause variable increases in CK-MM.

The presence of CK-MB in serum was once considered to be synonymous with myocardial infarction. We now know of several other cardiogenic and noncardiogenic causes of CK-MB in serum. However, the characteristic rise and fall of serum CK-MB activity in the proper clinical setting is still an accurate index of myocardial infarction. The isoenzyme appears in serum specimens from 3 to 6 hours after an infarct, peaks at 12 to 24 hours and generally disappears in 48 to 72 hours. Other cardiogenic causes of increased CK-MB activity in serum include cardiac operations, myocardial ischemia, myocarditis and cardiac trauma. Small increases in serum CK-MB activity have occasionally been seen with cardiogenic shock, cardiac catheterization, ventricular tachycardia, defibrillation and following stress testing.

Noncardiac causes of CK-MB activity in serum include myopathies and dystrophies of skeletal muscle, massive skeletal muscle trauma, ischemic and alcoholic rhabdomyolysis, malignant hyperthermia, hypothermia, carbon monoxide poisoning and Reye's syndrome. CK-MB may be found in the serum of neonates. Persistence of CK-MB in adult serum specimens with no apparent cardiac or skeletal muscle disease is rare. Tumor-associated CK-MB has been rarely seen in cases of adenocarcinoma of prostate, colon and lung and of rhabdomyosarcoma.

Several recent reports cite CK-MB activity in serum specimens of marathon runners before, during and after races. CK-MB activity in skeletal muscle of trained long-distance runners is greater than in controls and parallels serum activity. Technetium Tc 99m pyrophosphate scintigrams following marathons show no myocardial uptake but significant uptake in quadriceps muscles that suggests a skeletal muscle source.

CK-BB is rarely detected in serum specimens of adults but is commonly found in cord blood and neonatal serum specimens. CK-BB is frequently seen with cerebral anoxia associated with cardiogenic shock and, transiently, following a cardiopulmonary bypass surgical procedure. Patients who have sustained significant cerebral trauma may manifest serum CK-BB activity. CK-BB activity is seen in serum specimens from postpartum women from five to eight hours after delivery.

Of particular interest is the association of CK-BB with several malignant conditions. Homogenates of many epithelial, lymphoid and glial tumors contain significant CK-BB activity. Tumor-associated serum CK-BB is seen occasionally in cases of small-cell anaplastic carcinoma of pulmonary origin and prostatic adenocarcinoma. Other epithelial tumors may also elaborate this isoenzyme.

Abnormal isoenzymes of creatine kinase may be detected by electrophoresis. Macro-CK is a complex of CK-BB and an autoantibody to CK-BB that may migrate anywhere between CK-MB and a point cathodic to CK-MM. It may confuse interpretation of electrophoretograms and may elute with the MB fraction in chromatography systems, causing a false-positive result. Mitochondrial creatine kinase is another abnormal variant of macro-CK that should not be confused with CK-MB. It is rare and usually seen in gravely ill patients, many of whom have disseminated malignant disorders.

Gerald E. Simon, M.D.

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Fine-Needle Aspiration of the Breast

Optimal fine-needle aspiration biopsy of a palpable breast nodule requires three individual but inseparably linked diagnostic steps: biopsy, morphologic evaluation and final clinicopathologic correlation. The initial biopsy phase consists of precisely manually locating and immobilizing the nodule, puncturing the nodule by rapid needle movements with repeated redirection over one to three seconds, expelling the material onto glass slides and delicately spreading (versus smearing) the cells in monolayered sheets on glass slides. Generally, three such biopsy specimens in experienced hands can provide adequate sampling for most breast nodules. Although these intricate movements are detailed by Linsk and Franzen, words and illustrations cannot replace working with someone skilled in the procedure. Suboptimal biopsy technique is more likely to result in failure to diagnose carcinoma than is an inexperienced morphologic interpretation.

Because a specimen from fine-needle aspiration usually consists of clustered epithelial cells without accompanying fibrous stroma, the many criteria in surgical pathology that rely on the relationships between large groups of tumor cells and their accompanying stroma are of little use in this procedure. Fortunately, the excellent fixation afforded to the small aspirated cell groupings and the absence of paraffin-processing artefact common to routine pathology tissue sections render the directly stained fine-needle aspiration smears in crisp and reproducible cytologic detail. Typically, benign breast ductal cells have a small nucleus (about 1½ erythrocyte diameters), uniform nuclear placement and preserved intercellular cohesion. Malignant features are typically the opposite of one or more of these basic benign criteria. The various exceptions and diagnostic nuances can be learned through experience, as can their equivalents in surgical pathology.

The diagnostic features in aspirated material are best assessed in air-dried material processed with one of the metachromatic stains commonly used for hematology, such as Wright's stain. The consistent nuclear diameter and cytoplasmic detail in this fixation-staining system are perfect for three basic breast criteria. Nuclear chromatin detail available in alcohol-fixed and Papanicolaou-stained material, while the cornerstone of "classic" cytologic tests as in cervicovaginal smears, adds little to breast material from fine-needle aspiration. Indeed, the generally limited definition of cytoplasmic features offered by the Papanicolaou stain and the coexisting potential of air-drying artefact before alcohol fixation can be formidable diagnostic hindrances. Hematoxylin and eosin staining, the mainstay of surgical pathology tissue specimens, is undesirable in routine fine-needle breast aspirate for similar reasons.

Like the last movement of a symphony, the clinicopathologic correlation reviews and then develops all preceding information into a final statement. Here the clinical history, physical characteristics of the nodule, pattern of needle resistance, type or quality of material expelled from the needle, adequacy of smears and their staining and the microscopic appearance of these cells are all interwoven by an experienced practitioner to provide the most detailed diagnostic statement possible. In a sense, each needle aspiration biopsy procedure must conclude with the question, Does the material observed on microscopic examination adequately explain all the preceding clinical and gross biopsy findings?

When these three steps are optimally carried out by a trained and experienced physician, the false-negative rate is 2% to 6% and the false-positive rate is about 0.1%, in keeping with frozen-section diagnostic results. In discussions by pathologists and nonpathologists, there is ofen a tacit assumption that surgical excision diagnosis alone is infallible and provides the only "acceptable" method of diagnosing a palpable breast nodule. In fact, one investigator has shown that the false-negative rate of "benign" surgical pathology material may be as high as 2.4%. Moreover, a surgical pathologist can have false-positive frozen-section results.

If every "significant" breast nodule were to be surgically excised, the preceding discussion as to the relative accuracy of fine-needle aspiration versus surgical excision might be moot. Palpation, which is the common antecedent to surgical excision, is in fact less sensitive in reliably diagnosing carcinoma than is fine-needle aspiration. In one study the false-negative rates were 10% for palpation and 4% for needle aspiration. Although mammography has a significant role in evaluating nonpalpable breast nodules, its efficiency rate (true-positive plus true-negative results expressed as a fraction of the total population) for palpable nodules is reduced by many noncommittal ("suspicious") diagnoses. Indeed, any test's false-positive and false-negative rates can be reduced to zero if all test results are "suspicious". Under these circumstances, however, the efficiency (or general applicability of the test to broad patient populations) would be zero. Efficiency rates for fine-needle aspiration, palpation and mammography according to one study are 81%, 72% and 58% respectively.

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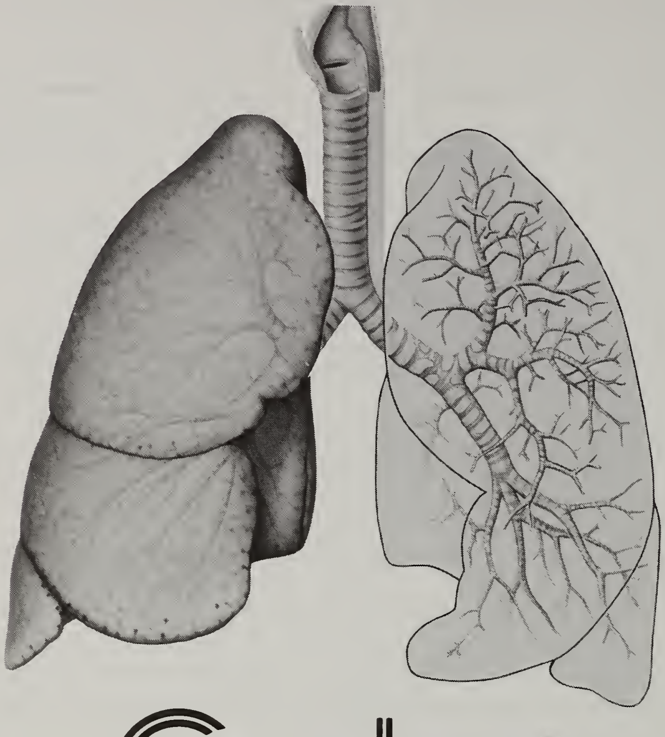

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Brief Summary. Consult the package literature for prescribing information.

Indications and Usage: Ceclor® (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor.

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: *General Precautions* — If an allergic reaction to Ceclor® (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy — Pregnancy Category B — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor® (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below:

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbiliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

Note: Ceclor® (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Organ Transplantation, Medical Technology Assessment and Resource Allocation

CLYDE J. BEHNEY, M.B.A. AND JANE E. SISK, PH.D.

Organ transplantation is clearly a dramatic area of medical science and technology. Advances in human organ transplantation are proceeding at an often rapid but sometimes frustratingly slow pace. Many applications are still considered experimental, e.g., by third-party payers such as Medicare and private health insurance companies. Heart transplantation is not presently covered by Medicare, pending the results of a major evaluation of its efficacy and safety. Pancreas transplantation is not covered, although it is presently under review by the Public Health Service. The Department of Health and Human Services recently deemed liver transplantation nonexperimental for children with certain conditions, thus paving the way for Federal and State payment. Cornea transplants are becoming more common and the procedure is covered by Medicare on a routine basis. And of course, kidney transplants have long been considered an established treatment, and a special program under Medicare covers them.

The question of "experimental" status is a difficult one, but most likely needs to be re-examined for the various forms of transplantation, due to recent advances in biomedical science. For example, it appears that improved success rates are occuring because of cyclosporine, improvements in pretransplant blood transfusion matching and techniques, and increases in surgeons' experience. This does not necessarily mean that all transplantation has moved beyond experimental status, nor does it eliminate the need to consider a large set of questions that go beyond clinical risks and benefits when making decisions about transplantation.

This paper will not focus on the specifics of individual transplantation procedures. Rather, it will take a broad perspective on the interactions among transplantation, technology assessment, and resource allocation. After presenting some brief material on human organ transplantation and on the types of issues raised by transplantation, we will discuss resource allocation and then cover the role and the potential contribution of medical technology assessment.

The Office of Technology Assessment (OTA) has conducted only a few specific studies of organ transplantation and artificial organs (e.g., status of cyclosporine, analysis of end-stage renal disease, and the artificial heart). Although this paper will draw upon that work, it will be most heavily based on OTA's work on the importance and status of medical technology assessment and on the process of resource allocation.

Issues Raised by Transplantation

Whatever their status, and whatever the pace of advance, each form of organ transplantation raises questions that need to be examined. Some questions are personal ones, to be faced by individuals. Others are for society and its institutions. Many must be considered by the Federal Government. A sample of the questions raised follows.

1. **Research and Development Questions.** Are we focusing on the most appropriate research areas? Are funding levels adequate? What is the balance between basic research, applied research, and technology development for any particular medical technology? Is this the best use of scarce research dollars?
2. **Efficacy and Safety Questions.** What types of evaluation of current and potential effects have been or need to be done? What are the technology's impacts on health (clinical benefit and risk) in the short term (e.g., successful transplant rates, operative mortality, complications, graft rejection) and in the longer term (e.g., long term survival, quality of life enhancements over time)? Who will ask the assessment questions; who will attempt to answer them; and who will act based on the answers? Are data adequate?

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3. **Adoption, Financing, and Use Questions.** Is the rate of adoption (initial entry of the technology into use) and then use appropriate? Are the populations most likely to benefit from the technology receiving its benefits, or is access skewed? Who will pay for technology's use? Are delivery systems inadequately or inefficiently organized? Donor identification and organ distribution are crucial issues here.
4. **Regulatory Questions.** What regulatory oversight is applicable to the technologies? E.g., what is the role of the Food and Drug Administration? What other Federal or State programs apply? What are or will be the effects of such regulation?
5. **Ethical, Legal, and Other Social Questions.** Organ transplantation raises many sensitive issues of ethics, law, psychology, religion, resource allocation, and so on. What social questions need to be asked in regard to the technology? Can they be raised in advance of the technolgy's diffusion? Can assessment provide helpful information? Who is responsible for making decisions relative to an organ transplantation technology's development, regulation, or use? And can they make such decisions taking into account the potential ethical and other social implications of the technology? Equity is a particularly important question in this area.
6. **Economic and Cost Issues.** Economic questions bring together many points raised above: Is a particular form of organ transplantation a "cost-effective" way to expend resources? Are financing and delivery systems efficient and equitable? What are the costs implications for society of transplantation, and what are the alternate possibilities for use of such funds? Will economic decisions be made openly and explicitly or will they be made implicitly, without public scrutiny?

Such a list of questions appears formidable, even though it represents only a sample of the questions raised by any medical technology. Nevertheless, they must be asked. Organ transplantation is too important for its development and use to proceed without full knowledge of goals and possible impacts on individuals and on society.

In the list above, many of the issues directly of concern to the Federal government are obvious: funds and priorities for basic and applied research and development; dissemination and development of data about organ transplantation and its benefits, risks, and costs; financing of treatment; helping to assure access and equity; and regulation.

Resource Allocation

Resource allocation is in essence a political activity and responsibility yet it can be informed by relevant information derived from analysis. Organ transplantation is an area where the allocation of scarce resources demands both quantitative and qualitative data and where social and political factors will always play by far the largest determining role.

One logical starting point that is often ignored or assumed away is the split between the amount of resources to be spent on health and on medical care as opposed to that allocated to all other sectors of society.[1] In the past, this choice has often been made implicitly, by ignoring it. This approach is changing, however, as society begins asking how much health care it can afford and who shall pay for it.

Today, however, we are more directly concerned with the allocation of resources within the area of health and health care. Even so, there is an entire series of possible ways to spend money. Few areas of medical technology point out so dramatically the tough nature of the choices to be made in allocating resources as does organ transplantation.

Consider the following list of ways to spend funds on organ transplantation and its alternatives for the related diseases. Funds could be distributed among:

- Basic research;
- Applied research and technology development;
- Evaluation of technologies' benefits, risks, costs;
- Development and funding of delivery and distribution systems;
- Health services research to improve delivery systems and financing of treatment;
- Development and operation of communications/data handling systems and creating and disseminating data on the technologies, delivery systems, individuals in need, and potential donors;
- Disease prevention (e.g., screening, health promotion);
- Treatment of disease through organ transplantation;
- Treatment of disease through artificial organs or through other alternatives to transplantation; or
- Efforts to increase public understanding of transplantation and organ donation.

Like it or not, when we choose to spend a certain amount on any particular one of these categories, we are denying it to others—perhaps not directly, perhaps not explicitly. When we choose among these possibilities, we are making judgments about their relative values as "investments" of our scarce dollars, even though these judgments may be implicit or hidden. Specific relative spending patterns reflect judgments on the value of "health," on the value of extending life, on the value of enhancing quality of life, on the value of reducing expenditures (of making cost-beneficial decisions), on the value of enjoyment now versus added years of life later, and on the value of our image (of ourselves as individuals or as members of a human society), and many others (such as the value of being a research-oriented people).

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[1] Even this basic choice is not at all clear. For example, the effects of environmental quality, urban security, housing, lifestyle, and so on may be quite dramatic in terms of health.

The critical problem arises when judgments that reflect a high value on positive economic outcomes conflict with those that reflect a high value on other outcomes (equity, quality of life, humaneness). The priorities will not always be at odds. Investment in basic research is considered by many people to be a sound financial investment. But conflicts will arise in many or most cases. The result is that we cannot do all the things that we would like to do as members of a caring society.

This split between economic goals and health or human goals becomes especially acute in a field such as transplantation because transplantation is a prime example of what Dr. Lewis Thomas has called "halfway technologies." Halfway technologies are not cures; they do not eliminate the cause of disease. Rather, they are in some important senses crude attempts *to make up for* the disease or condition. And, like most halfway technologies, organ transplants are expensive and raise profound issues of resource allocation and moral and social dilemmas.

This clash between limited resources and medical and social goals is one major reason why resource allocation, especially in the area of organ transplantation, is and needs to be in large part a social responsibility. As mentioned below, choices can be helped by formal analysis and data, but—the fact will always remain—analysis of costs and benefits will not tell us how to spend our resources. No cost-effectiveness or cost-benefit calculus can usurp the position of social and political decision makers.

Medical Technology Assessment and Organ Transplantation

Medical technology assessment—whether of health benefits and risks, or of costs, or of social implications—can at the most provide decision makers with more information on which to make their decisions. It can help in showing what is known; it can point out uncertainties and assumptions; and it can sometimes help draw the dividing line between what can be decided on the basis of research evidence and what must be decided in the social or political arena.

In order to make the best decisions possible, society's decision makers must have the best information that is available or can be developed. Medical technology assessment can be of particular help in providing the following types of information. Some will be relatively direct and quantitative; other types will be less definitive and more qualitative.

- Data on a transplant technology's efficacy (its clinical benefits) in terms of health outcomes (mortality reduction, quality of life changes, etc.);
- Data on both short-term and long-term risks of the technology;
- Some measure of the costs of applying the technology, both in relation to alternatives to transplantation and in terms of the potential aggregate costs to society and the specific costs to individuals.
- Information on the structure and operation of the systems for gathering and preparing organs and the systems for delivering the transplant technology;
- Information on disease prevention and health promotion as alternatives to treatment (through both transplantation and other forms of treatment)—especially information on benefits, risks, and costs relative to treatment;
- Primarily qualitative information on potential social and ethical implications of transplantation or lack of transplantation;
- Estimates of fruitful areas of basic research and applied research and technology development in which to invest funds; and
- Ideally, some characterization or *practical* estimates of the near term future of disease patterns, population changes, technological advances, and social institutions changes.

These types of information may help to make decisions more rational. They will rarely if ever point to a particular decision (other than a clinical one on occasion). Some of the needed information exists, but much more is needed.

We should face our ignorance. Decisions related to transplants are tricky and there are many gaps in our knowledge. At the same time, developing and disseminating information is an expensive task. We cannot develop all the possible information about every type of transplant technology. Compromises and judgments about the most helpful data will have to be made.

The Federal government has two important roles in medical technology assessment. One is the broad function of protecting the public health and promoting the general welfare. Funding of biomedical research and general medical technology assessment activities fall under this responsibility. The Federal government also has a specific role in the Medicare program to assure that all reasonable and necessary care is available to beneficiaries. In both cases, the central task of technology assessment is to assure two goals: 1) that technologies provided to the public be known to be efficacious and safe; and 2) that all technologies known to be efficacious and safe are broadly available.

In examining the Federal Government's activities in medical technology assessment, OTA has used a simple model of information development and flow:

- Identification—Monitoring technologies, determining which need to be studied, and deciding which to study.
- Testing—Conducting the appropriate analyses or trials.
- Synthesis—Collecting and interpreting existing infor-

mation and the results of the testing stage, and, usually, making recommendations or judgments about appropriate use.

- Dissemination—Providing the synthesis of information, or any other relevant information, to the appropriate parties who use medical technology or make decisions on their use.

In its 1982 report, *Strategies for Medical Technology Assessment,* OTA found the Federal Government's activities to be inadequate in a number of areas. Only drugs and devices are examined in a systematic way as part of the activities of the Food and Drug Administration. The Congress addressed these problems in 1978 in passing legislation to establish the National Center for Health Care Technology (NCHCT), but budget cuts led to NCHCT's dissolution in 1981. Although a remnant of NCHCT, the Office of Health Technology Assessment (OHTA), still handles Medicare coverage decisions for the Public Health Service, many problems remain unaddressed. There is in fact no systematic identification of medical and surgical procedures needing assessment. Investments in testing, such as clinical trials, are small relative to the needs for information. Synthesis activities are generally underdeveloped. And dissemination of results has actually been cut back in the past few years.

But perhaps the greatest problem is the lack of a systematic approach to the general problem of medical technology assessment. Such activities as there are function with little relation to each other.

Conclusion

There are many issues in our pluralistic society that are dealt with in a fragmented way, with the involvement of different public and private individuals and groups. However, the case of organ transplantation illustrates the drawbacks of that approach for at least this area of medical technology assessment and resource allocation.

Support for a more purposeful approach is widespread. The Administration helped to establish the American Council on Transplantation, a private organization designed to coordinate the procurement of organs for transplantation. Several bills introduced into Congress would address the problems by such means as studying the range of issues related to transplantation, expanding activities to procure organs and to match them with recipients, establishing a national transplantation registry, or prohibiting the purchase and sale of organs for transplantation. But despite a consensus that improvements are vital and possible, sharp disagreements remain about the appropriate role of the Federal Government and the extent of centralized activity needed.

Organ transplantation thus provides a dramatic example of the complex issues associated with medical technology assessment and resource allocation and, at least to date, the difficulty that our political institutions have in dealing with them.

STATE MEDICAL SOCIETIES are being canvassed to determine the effect of federal antitrust laws on their ability to respond to patient complaints about inappropriate charges or services from physicians. When compiled, the information may comprise the basis for a request for an advisory opinion or for a business review letter providing guidance to medical societies. Responding to Resolution 77 (A-84), which called on the AMA to seek immediate relief from the antitrust laws that prevent the Association from representing and negotiating for its members, the board is providing physicians with information on strategies they may pursue within the constraints imposed by the antitrust laws. At the Interim Meeting in December, the House of Delegates will consider board reports on collective bargaining agents and incorporation of hospital medical staffs. Pending legislative action on proposed amendments to limit the jurisdiction of the Federal Trade Commission, the board said it would be "unwise to seek broader statutory protection . . . at this time."

—AMA *Newsletter,* October 23, 1984

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Gastrointestinal: Nausea,* epigastric pain,* heartburn,* diarrhea, abdominal distress, nausea and vomiting, indigestion, constipation, abdominal cramps or pain, fullness of GI tract (bloating and flatulence); **Central Nervous System:** Dizziness,* headache, nervousness; **Dermatologic:** Rash* (including maculopapular type), pruritus; **Special Senses:** Tinnitus; **Metabolic/Endocrine:** Decreased appetite; **Cardiovascular:** Edema, fluid retention (generally responds promptly to drug discontinuation; see PRECAUTIONS).

Incidence less than 1%—Probable Causal Relationship**

Gastrointestinal: Gastric or duodenal ulcer with bleeding and/or perforation, gastrointestinal hemorrhage, melena, gastritis, hepatitis, jaundice, abnormal liver function tests; **Central Nervous System:** Depression, insomnia, confusion, emotional lability, somnolence, aseptic meningitis with fever and coma; **Dermatologic:** Vesiculobullous eruptions, urticaria, erythema multiforme, Stevens-Johnson syndrome, alopecia; **Special Senses:** Hearing loss, amblyopia (blurred and/or diminished vision, scotomata, and/or changes in color vision) (see PRECAUTIONS); **Hematologic:** Neutropenia, agranulocytosis, aplastic anemia, hemolytic anemia (sometimes Coombs positive), thrombocytopenia with or without purpura, eosinophilia, decreases in hemoglobin and hematocrit; **Cardiovascular:** Congestive heart failure in patients with marginal cardiac function, elevated blood pressure, palpitations; **Allergic:** Syndrome of abdominal pain, fever, chills, nausea and vomiting; anaphylaxis; bronchospasm (see CONTRAINDICATIONS); **Renal:** Acute renal failure in patients with pre-existing significantly impaired renal function, decreased creatinine clearance, polyuria, azotemia, cystitis, hematuria; **Miscellaneous:** Dry eyes and mouth, gingival ulcer, rhinitis.

Incidence less than 1%—Causal Relationship Unknown**

Gastrointestinal: Pancreatitis; **Central Nervous System:** Paresthesias, hallucinations, dream abnormalities, pseudotumor cerebri; **Dermatologic:** Toxic epidermal necrolysis, photoallergic skin reactions; **Special Senses:** Conjunctivitis, diplopia, optic neuritis; **Hematologic:** Bleeding episodes (e.g., epistaxis, menorrhagia); **Metabolic/Endocrine:** Gynecomastia, hypoglycemic reaction; **Cardiovascular:** Arrhythmias (sinus tachycardia, sinus bradycardia); **Allergic:** Serum sickness, lupus erythematosus syndrome, Henoch-Schönlein vasculitis; **Renal:** Renal papillary necrosis.

*Reactions occurring in 3% to 9% of patients treated with *Motrin.* (Those reactions occurring in less than 3% of the patients are unmarked.)

**Reactions are classified under *"Probable Causal Relationship (PCR)"* if there has been one positive rechallenge or if three or more cases occur which might be causally related. Reactions are classified under *"Causal Relationship Unknown"* if seven or more events have been reported but the criteria for PCR have not been met.

Overdosage: In cases of acute overdosage, the stomach should be emptied. The drug is acidic and excreted in the urine so alkaline diuresis may be beneficial.

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Transplantation

FRANK P. STUART, JR., M.D., F.A.C.S.

Rejection of organ allografts (homografts) is a normal response that transplant surgeons try to prevent or control by reducing the genetic disparity between donor and recipient (matching) as much as possible and by suppressing the recipient's immune response to the remaining disparity. Matching is particularly attractive because it is safe. Yet, as the science of tissue typing develops, the number of cell-surface antigens known to affect rejection has increased to the point where meaningful matching is difficult to achieve. While matching has become more problematic, immunosuppression has become safer and more selective.

Typing and Matching

Until the past year, it has been nearly a dogma for kidney transplantation that recipient and donor must be matched for erythrocyte A and B antigens in order to avoid abrupt injury of the graft by circulating anti-A and anti-B antibodies. The targets for the antibody seem to be erythrocytes of donor origin trapped in the microcirculation of the kidney when it is removed from the donor. Also, vascular endothelial cells in the donated kidney may transiently express the A and B antigens of the donor on their surface and be a target for antibody-mediated injury. Thus, a patient with blood type AB was a universal graft recipient, and a graft from a type O donor could be accepted by anyone.

During the past year several centers have reported that removal of circulating anti-A or anti-B antibodies by plasmapheresis of the recipient 12 to 24 hours before transplantation will prevent injury of the kidney in the face of ABO mismatch between donor and recipient. It is likely that pretransplant plasmapheresis of the recipient will obviate the need for ABO matching of all organ grafts.

Typing of cell-surface antigens determined by the HL-A locus is what is generally referred to as tissue typing. The HL-A region is a segment of the sixth chromosome, about 300 genes long, whose alleles determine two classes of cell-surface glycoproteins or histocompatibility antigens. Class I antigens are found on all nucleated cells and are the ultimate targets of rejection. They are determined by alleles expressed at the A,B, and C gene sites, or loci, of the HL-A region. Despite much early optimism, matching of class I antigens had added little or nothing to survival of cadaveric organ grafts in a population as heterogeneous as that found in the United States.

Class II antigens are restricted largely to cells of the immune system. They are not the primary targets for rejection; rather class II disparity between donor and recipient regulates the intensity of the rejection against class I antigens. Class II antigens are determined by alleles expressed at the DR, DC, and SB gene sites, or loci, of the HL-A region. Some reports claim that DR matching increases survival of cadaveric organ grafts by 10 to 20 percent. However, well-controlled studies are lacking, and few centers have begun to match for DC and SB as well as DR antigens. Matching for all three class II loci (DR, DC, and SB) would introduce such a large number of allelic combinations that a "good" match would be difficult to find between the unrelated donor and recipient.

Crossmatching between the recipient's serum and the donor's peripheral blood target cells is the third and last feature of typing and matching. Some individuals have circulating antibodies against class I and class II antigens of other people; that is, they are already immunized against or presensitized to others. Preformed antibodies against a donor's class II antigens do not harm and might even promote graft survival. However, preformed antibodies against a donor's class I antigens usually cause abrupt or accelerated graft rejection. A new method has been reported during the past year that permits much more accurate measurement of preformed anti-class I and anti-class II antibodies in the potential recipient's serum. The method, known as flow cytometry, uses fluorescent labelled monoclonal antibodies and will probably become a standard part of routine crossmatching within the next few years.

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Immunosuppression

The long-sought goal of immunosuppression is to block only the response to antigens introduced by the donor graft without depressing other normal protective responses against pathogens. That goal hasn't been realized yet, but we are closer to it. Azathioprine and prednisone suppress the entire immune system and have serious side-effects on other systems (intestinal epithelium, bone marrow, ocular cataracts, osteonecrosis, and granulocyte function). These drugs will be largely replaced in 1984 by a new drug, cyclosporine. Cyclosporine acts mainly on thymus-derived lymphocytes, cells that are responsible for rejection. It leaves some other elements of the immune system intact and has far fewer and less severe side-effects than high doses of azathioprine and prednisone. However, cyclosporine still suppresses much of the normal defense against viruses just as azathioprine and prednisone do. Cyclosporine is especially effective in controlling the early or inductive phase of the rejection response that occurs within the first few months after transplantation. Beyond the sixth post-transplant month, several recent reports suggest, small and relatively safe doses of azathioprine and prednisone may be almost as effective as cyclosporine for long-term protection of the graft. The maintenance dose of cyclosporine costs $15 a day and is about 20 times more expensive than azathioprine and prednisone. Most insurance plans and Medicare do not reimburse the cost of outpatient drugs. Unless the recipient can afford $5,000 a year for cyclosporine, he may be obliged to convert to azathioprine and prednisone for long-term maintenance.

Monoclonal antibodies have been developed against an array of human T-lymphocyte surface antigens. Several are being tested for their ability to reverse rejection episodes. They seem to be quite effective at reversing the initial episode, but many patients quickly experience a second rejection that must be treated with steroids. Clinical trials approved by the Food and Drug Administration (FDA) will continue to evaluate the role of monoclonal antibodies for therapy. Meanwhile, a polyvalent anti-thymus globulin (ATGam) was approved by the FDA in late 1982 and is at least as effective as steroids at reversing rejection; it even reverses some steroid resistant rejections.

Kidney Transplantation

The crucial first-year survival figure for kidney transplants ranges among various transplant centers from 75 percent to 95 percent for related donors and 50 percent to 80 percent for cadaver donors. The better results achieved in some centers appear to be due to the cumultive effect of several variables in pre- and post-transplant management. These are pretransplant splenectomy, pretransplant and intraoperative transfusions (either random donor or donor specific, for those with a related-donor kidney graft), DR matching, and addition of antilymphocyte globulin to early postoperative immunosuppression.

Cyclosporine may reduce the importance of these management variables. The four transplant centers in the United States that have studied cyclosporine have achieved remarkably similar graft survival despite major differences in the use of splenectomy, matching, transfusions, and antilymphocyte globulin; typically, graft survival at one year is 90 to 95 percent for related grafts and 75 to 80 percent for cadaveric grafts in recipients treated with cyclosporine. It is likely that selection, preparation, and management of kidney-graft recipeints will be greatly simplified during the coming year.

The total cost for a kidney transplant and followup care for the first year is about $35,000. This cost will fall, but already compares favorably with that of chronic dialysis, which each year is about $25,000 for the dialysis alone and another $10,000 to $20,000 for hospitalizations related to vascular access problems or other complications of end-stage renal disease. Given the cost-effectiveness of kidney transplantation, the number of kidneys transplanted at 150 centers in the United States should increase from approximately 5,500 in 1983 to 15,000 to 18,000 each year. Twenty-two thousand Americans get end-stage renal disease each year and begin chronic dialysis treatments. At least 75 percent of them will be candidates for kidney transplantation in the cyclosporine era.

Heart and Lung Transplantation

Between December 1967 and January 1984, more than 900 patients received heart transplants throughout the world. Approximately one-third were performed at Stanford University, one-third at other United States centers, and one-third outside the United States. Since December 1980, cyclosporine has replaced azathioprine as the primary immunosuppressant at Stanford. It has been used with a lower dose of steroids and has been associated with a higher survival rate; 83 percent of recipients are surviving for at least one year and 72 percent beyond two years. Eighty percent of those surviving enjoy unrestricted physical activity. In sharp contrast, the average patient waiting for a heart transplant survived only three months without a transplant and none survived for a year.

In addition to Stanford, six other centers in the United States had performed more than 20 heart transplants by the end of 1983. The average first-year cost of a heart transplant with cyclosporine is $55,000, approximately twice the cost of coronary artery bypass surgery. The National Heart, Lung and Blood Institute no longer considers heart transplantation to be experimental and does not provide research funds for the operation or for post-transplant care. By the end of 1984, at least 20 centers in the United States will have made serious commitments to heart transplant programs. The major problems remaining to the evolution of clinical heart transplantation are an extreme shortage of hearts and resistance by many insurance companies and other third-party carriers to recognize the procedure as therapeutic and generally accepted by the medical profession.

Liver Transplantation

By the end of 1983, approximately 700 liver transplant operations had been performed in the world. Half were performed by a single team at The University of Colorado-University of Pittsburgh. Four other centers in the United States had each performed 5 to 15 liver transplants. The University of Cambridge has the second largest experience in the world (180 liver transplants) and centers in Hanover and Groningen have performed 80 and 25 liver transplants respectively.

In 1980, cyclosporine replaced azathioprine as the primary immunosuppressive drug in the Pittsburgh program. It has been used with low doses of prednisone and has had a dramatic effect on recipients of liver transplants. Since 1980, 70 percent of patients have survived at least one year and 60 percent survive more than two years. Patients placed on the waiting list who fail to receive a transplant rarely survive more than six months.

"By the end of 1983, approximately 700 liver transplant operations had been performed in the world."

In mid-1983, a Consensus Development Conference sponsored by the National Institute of Health concluded that liver transplantation was therapeutic and should be made much more available. The average cost of liver transplantation at The University of Pittsburgh since introduction of cyclosporine has been $80,000. Starzl has pointed out that the transplant costs are frequently dwarfed by the hospital costs incurred in treating progressive liver failure. As in the case of heart transplantation, the major obstacles remaining to liver transplantation are a shortage of organs and resistance by many insurance companies and other agencies, such as Medicare and Medicaid, to recognize liver transplantation as therapeutic and generally accepted by the medical profession. Nevertheless, at least 10 medical centers in the United States will have made a serious commitment to liver transplant programs by the end of 1984.

Pancreas Transplantation

The clinical role is not yet as well established for transplantation of the pancreas as it is for the heart and liver. Slightly more than 300 pancreas transplants have been performed since 1966. At least 50 were infusions of isolated islets rather than surgical transplantation of the organ itself. Despite early optimism and high expectations, the recipients of isolated islets continue to require exogenous insulin. Although islet transplantation is still an attractive alternative that will probably be effective eventually, its clinical application has been set aside temporarily in favor of transplanting either the whole pancreas or its distal segment. Consensus has not yet been reached on technical matters, such as drainage of exocrine secretions, site of implantation, whether to include the duodenum and/or spleen, and whether or not to transplant the pancreas and kidney at the same time in type I diabetics with end-stage renal disease.

Nearly 75 percent of the experience with pancreatic transplantation in the United States is concentrated at The University of Minnesota where the procedure was first introduced in 1966. The current approach at Minnesota is to defer pancreas transplantation until one or two years after successful kidney transplantation in the type I diabetic. In the recipients of pancreas transplants treated with cyclosporine at Minnesota, only 30 percent of the pancreas grafts have functioned normally beyond the first post-transplant year.

It is not clear why the same immunosuppressive regimen is less effective for pancreas transplants than for kidney, liver, and heart transplants. Several reports on experimental animals and man suggest that the pancreas is no more prone to rejection than the kidney is when they are transplanted concurrently. But, concurrent transplantation of both organs is technically demanding and has been avoided mainly for fear of increased complications other than rejection. Perhaps cyclosporine, with its reduced prednisone requirement, will encourage renewed interest in concurrent transplantation of the pancreas and kidney.

Short-term Preservation

The kidney can be preserved safely for 48 to 72 hours by either of two methods. The first cools the kidney quickly to 4 to 8 °C and then perfuses the kidney continuously with a cold, oxygenated electrolyte solution that contains dextrose, albumin or plasma, and other additives. The second method calls simply for an initial cold flush with a solution that mimics intracellular fluid. The kidney is then stored at 4 to 8 °C. With both methods, approximately one-third of the recipients will require temporary post-transplant dialysis.

"The human heart and liver cannot be preserved as easily as the kidney. Continuous perfusion has not been helpful for either organ."

The human heart and liver cannot be preserved as easily as the kidney. Continuous perfusion has not been helpful for either organ. Rather the heart and liver are cooled rapidly by immersing and/or flushing with cold electrolyte solutions of extracellular composition and transplanted as quickly as possible. The length of time outside a body rarely exceeds three hours for the heart or eight hours for the liver. Little progress has been made on this serious problem during the past year.

Potential Supply of Organ Donors

Control of rejection has been eclipsed by insufficient cadaveric organs as the number one problem in transplantation. The number of kidney transplants could treble during the next few years if there were enough kidneys available. Liver and heart transplantation could each reach 5,000 a year by the end of the decade. Is the potential number of cadaver donors large enough to meet these projections.?

Studies conducted by the Centers for Disease Control (CDC) of the U.S. Public Health Service suggest that at least 12,000 deaths, and perhaps as many as 27,000 deaths, occur each year in hospitals in the United States under circumstances that would permit easy retrieval of transplantable organs. The studies concluded that the small number of transplantable cadaver kidneys retrieved was not attributable to lack of suitable organs but rather to failure to identify suitable donors, obtain consent, and retrieve the kidneys.

In a second study conducted from 1976 to 1979, the CDC undertook a collaborative project with two transplant programs in Georgia to increase the retrieval of cadaveric kidneys in 34 hospitals. After intense efforts between transplant programs and the hospitals, the overall retrieval increased from six to 16 percent of potential donors, which is what the nationwide retrieval rate is at present. Despite the increased general awareness that resulted from the CDC study, only 42 percent of the potential donors identified were actually referred to a transplant program. Family consent was obtained in only 47 percent of those referred. Kidneys were then retrieved from 81 percent of the potential donors whose families consented (19% were lost because or cardiovascular instability before the kidneys could be retrieved).

The major barrier to maximum retrieval of kidneys (and other organs) is the compound effect of insufficient referrals and refused consent, which together exclude 80 percent of potential donors. In general, physicians and surgeons responsible for the care of patients with lethal head injuries and strokes would rather not be bothered with the whole issue of organ retrieval. A survey of intensive-care nurses revealed that 87 percent of the nurses approved of organ donation and retrieval. However, only 64 percent thought their hospital director was in favor or it and only 42 percent thought the neurologists and neurosurgeons in their hospital approved of it.

No single action will lead to retrieval of sufficient numbers of cadaver organs for transplantation. Rather, we must approach the problem from many directions. Among the possible initiatives are donor cards; education of the general public as well as the professionals who care for the ill and injured about organ donation and transplantation; laws that accept brain death as a basis for declaring death; better identification of potential donors; regulations that require hospitals of a certain size to facilitate organ retrieval; and, finally, consideration of laws that presume consent to remove transplantable organs after death.

Although many hospitals may have no specific objection to organ retrieval, they may avoid participation in a retrieval program unless it is required by a regulatory agency. State hospital licensing boards may be the appropriate governmental agencies to set standards for organ retrieval programs. Licensing boards are a part of the executive branch of state government. As much, they are concerned with the larger social, economic and humanitarian implications of what transpires within hospitals. The Centers for Disease Control have already shown that 91 percent of the potential donors in two large metropolitan areas can be found in 13 percent of the area's larger hospitals. Exclusion of hospitals with fewer than 200 deaths each year from licensing regulations that require participation in organ procurement programs would seem to be a reasonable position.

In 1970, Dukeminier noted that a continued short supply of cadaver organs will inevitably increase the pressures to buy spare organs, such as a kidney or a segment of intestine, from willing, living, unrelated persons. Although the sale or organs by live donors or by the next of kin after the donor's death is repugnant to most people, it is not dealt with by the Uniform Anatomical Gift Act. Sale of organs by unrelated live donors is not forbidden by any state. Only Georgia specificaly forbids the sale of cadaver organs. At present it is only the unwritten code of ethics of transplantation surgeons that prevents the sale of live, unrelated, cadaver organs. Increased success in transplantation has placed tremendous pressure on transplant surgeons to modify their opposition, at least to the willing, living, unrelated donor. We are at the point where, as Dukeminier states, "Society must face the fact that cadaver organs can be used to save human life and that a hard choice must now be made. It must decide whether to advance the policy of preserving life or to stand paralyzed by its taboos."

Dukeminier's prediction of schemes to sell organs finally surfaced in late 1983. The public is generally opposed to sale of organs and the medical profession is almost unanimously opposed to it. We urgently need some imaginative approaches to make available to those in need the thousands of viable, transplantable organs that are now buried each year.

Medicare and Medicaid Budget Reconciliation Amendments of 1984

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Although the Medicare and Medicaid Budget Reconciliation Amendments of 1984 are brief by comparison with The Tax Reform Act of 1984, they contain several provisions which will very significantly affect most physicians. The Medicare and Medicaid law changes, like the tax law changes, were signed by the President July 18, 1984. Here is a summary of most of those Medicare and Medicaid provisions which directly affect physicians or have a significant indirect effect on them.

Physicians' Fee Freeze

Of greatest interest to physicians is the rather complex set of limitations and incentives concerning physicians' fees for treatment of Medicare beneficiaries. The themes underlying this section of the law are a reduction of the Medicare system's costs and pressure on physicians to agree to accept uniformly assignment for their treatment of Medicare patients.

From July 1, 1984, to October 1, 1985, prevailing and customary charge levels recognized by the Medicare carriers and used to determine Medicare's reimbursement to physicians and/or patients are frozen. The levels which will remain in effect until October 1, 1985, reflect charges from 1982.

The new law also introduces the term "participating physician." Each year physicians will have the opportunity to sign a contract with the Department of Health and Human Services (HHS) agreeing to accept assignment for *all* services to Medicare beneficiaries for 12 months. The first such contracts will cover October 1, 1984, through September 30, 1985. Newly licensed physicians or physicians who have moved can sign such a contract effective for a less than 12-month period.

The "participation" concept is important since the law also freezes non-participating doctors' charges to Medicare beneficiaries during the same 15-month period (July 1, 1984 to October, 1985). Penalties can be imposed upon a non-participating physician who during the 15-month freeze period "knowingly and willfully" charges a Medicare beneficiary a higher fee than he or she charged for the service during the second quarter of 1984. Fines of up to $2,000 per instance of higher fee charged may be imposed, and in severe cases doctors might be excluded from the Medicare program for up to five years. Such an exclusion would mean that neither the physician nor his or her Medicare beneficiary patients could obtain payments from the Medicare program.

The law does not specify how the base line for the freeze—a physician's "actual charges for the calendar quarter beginning on April 1, 1984"—is to be determined. The Medical Group Management Association has petitioned the Health Care Financing Administration (HCFA) to define that base line as the highest actual charge billed for the service to a Medicare beneficiary within that period.

HHS was directed to exercise discretion in imposing these drastic penalties. Although the law states that this freeze began to apply July 1, 1984, its limitation of the sanctions to physicians who "knowingly and willfully" violate this freeze, considered together with the Congressional direction to HHS to "make every effort to notify physicians, on a timely basis, concerning the requirements of this provision," indicate to us that the sanctions should not be imposed on any physician for charges made before he or she has received notice from the Medicare carrier about this freeze. Despite the likelihood of direct notice from Medicare, however, physicians who have made increased charges to Medicare patients after July 1, 1984, should probably

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roll back those increase (for Medicare patients) as soon as possible.

The very stiff fines will be the usual penalty levied, with exclusion from the Medicare program being used only "in extreme circumstances." Other circumstances expected by Congress to be taken into account by HHS include "whether a pattern of increased charges has occurred, the extent to which the patient faced increased costs as a result, and whether the amounts of the increases are significant." The sanctions are to be applied "vigorously but prudently."

Despite the prudence supposed to be exercised in imposing penalties, we advise any non-participating physician to take great care to see that no Medicare beneficiaries are charged more than this law allows.

We hope that HCFA will issue guidelines excepting some situations from the profile and/or fee freeze. For example, one of our clients recently installed costly new diagnostic equipment, but appears to be limited by the law to no more than its second quarter, 1984, charges, even though the new equipment will provide much better information than was attainable with the old equipment. We hope that these physicians will be allowed to recover the costs of this equipment by increasing fees. This client is seeking an opinion letter from HCFA under the circumstances, and we expect that many other non-participating physicians whose circumstances are out of the ordinary will want to do the same.

Participation Agreements

Every physician who serves any Medicare beneficiaries will be faced with the decision whether or not to become a participating physician. Participating doctors must accept assignment for all Medicare patients, while non-participating doctors will continue to have the traditional case-by-case election.

Signing the participation agreement could result in a substantial loss of income to physicians who have not traditionally accepted assignment. The law, however, contains measures to put pressure on physicians to participate.

The 15-month freeze on actual physician charges to Medicare beneficiaries does not apply to a participating physician. Therefore, a physician who signs a participation agreement for the October 1, 1984, to October 1, 1985, period will be allowed to raise any of his or her fees on or after October 1, 1984. While there would be no immediate financial benefit, those increased fees would be used to update the doctor's customary profile in October, 1985. If a non-participating physician raises his or her fees during the freeze period despite the panalties, any increase will not be recognized in determining his or her customary charge level used to compute the Medicare system's reimbursement for his or her services beginning October 1, 1985. Patients will therefore find it even more financially disadvantageous to patronize non-participating doctors.

HHS has also been directed to publicize widely the names of physicians who participate, both by publishing directories (to be available in any Social Security office, in the offices of Medicare carriers and for senior citizen organizations) and by requiring each Medicare carrier to maintain a toll-free telephone number so that Medicare beneficiaries may obtain the names, addresses, specialties and telephone numbers of participating doctors. HHS is directed to notify all Medicare beneficiaries of the publication of the directories.

The law also provides that annually the government will publish a list containing the name, address, specialty and percent of claims submitted on behalf of each physician during the preceding year for which the physician accepted assignment.

Thus the dis-incentives for non-participation are strong, primarily from a marketing standpoint, but the immediate loss in income to a physician if he or she participates may also be great. Most physicians will want to weigh the short and long term impact on their practices before deciding what choice to make.

Other Medicare and Medicaid Changes

Some other sections of the new law may significantly affect some physicians.

Laboratory Tests. The law limits Medicare's reimbursement for clinical diagnostic laboratory tests performed on or after July 1, 1984. A national fee schedule for tests performed in physicians' offices or in independent laboratories will be imposed July 1, 1987. During a three-year transition period, fee reimbursement will vary by region.

Beginning July 1, 1984, Medicare will reimburse lab tests conducted in physicians' offices based upon a fee schedule initially set at 60 percent of the current prevailing charge level. Tests performed in independent clinical labs will be reimbursed at the same rate this year. The schedules are then adjusted annually to reflect changes in the urban Consumer Price Index, and may be adjusted by HHS in certain special circumstances.

Physicians will now be able to bill for clinical laboratory services only if a physician directly supervises performance of the test. If a physician participates in Medicare, or chooses to accept assignment for lab tests, Medicare reimbursement to him or her will be 100% of the fee schedule amount described above, and no co-insurance or deductible requirement will apply.

Physicians without in-office labs may continue to bill a "nominal amount" to cover specimen collection and handling fees. The Medicare system will pay this fee only once per patient encounter.

States administering Medicaid programs will lose Federal funds unless they also limit reimbursement for lab tests to that permitted by the Medicare system effective October 1, 1984.

CRNA Costs Reimbursement. Anesthesiologists will be affected by new rules for reimbursement for costs of employing certified registered nurse anesthetists (CRNAs). For hospital cost reporting periods beginning on or after October 1, 1984, and before October 1, 1987, hospital costs of employing CRNAs will no longer be incorporated in their Diagnosis-Related Group (DRG) payments. Instead, costs for employing CRNAs can be passed through to their Medicare carriers as under pre-prospective payment rules.

While not in the law itself, the Congressional conference committee report indicates that for the same time period, where the anesthesiologists employ CRNAs directly, they will be permitted to bill one time unit for each 15 minutes of CRNA medical direction regardless of whether or not the CRNA was employed in the last cost reporting ending before October 1, 1983. This is a change from the TEFRA implementing regulations which played havoc with arrangements for CRNAs.

Medicare Studies. The deadline for HHS to report to Congress on the advisability and feasibility of making payments for physician services furnished to hospital inpatients based on the DRG system is advanced to July 1, 1985, by the new law.

Another study also required by December 31, 1985, will cover revision of the Medicare system's payments for physician services. This study is to examine the elimination of inequities in the relative amounts paid to physicians by type of service, locality and specialty, with particular attention to be paid to inequities between cognitive services and medical procedures. Also to be examined are additional incentives for physicians to accept assignment for services provided to Medicare beneficiaries and methodologies for the development of national or regional fee schedules for Medicare payments to physicians.

Teaching Physicians. A new floor is set for customary profiles for physicians in teaching hospitals. Regardless of historical charges, customary profiles will be at least 85% of the prevailing charges. Furthermore, if all the teaching doctors in a hospital agree to accept assignment for all their services to Medicare beneficiaries, then the Medicare reimbursement will be 90% of the prevailing charges paid for similar services in the area. These amendments apply to services furnished on or after July 1, 1984.

Miscellaneous. New limits are placed on how often reimbursement will be made for transtelephonic monitoring of cardiac pacemakers beginning October 1.

Reimbursement will be permitted for outpatient physical therapy services for patients under the care of a podiatrist, and for outpatient ambulatory surgery by a dentist or podiatrist in his or her office.

A physical therapist is now allowed to establish a plan of care for outpatient physical therapy services reimbursable by the Medicare system, although a physician must still periodically review all such plans of care.

Conclusion

We have attempted to mention most of the provisions of the "Medicare and Medicaid Budget Reconciliation Amendments of 1984" which directly affect physicians. There are other provisions of the law which directly affect hospitals and which may indirectly affect physicians' practices. Although most of the minor changes are quite straightforward, a great deal of interpretation is needed for the most significant provision, the physician fee freeze. Most physicians will want to be in touch with their advisors as this interpretation is issued in the coming weeks.

Month in Washington

Slowdown in Health Spending

Americans spent $313.3 billion for personal health care services last year, according to new statistics from the Department of Health and Human Services. When research and construction dollars are added total U.S. spending for health care amounted to $355.4 billion or $1,459 a person.

This 10.3% increase in total health spending over the prior year was the lowest in a decade and compared with increases of 12.5% in 1982 and 15.3% in 1980. Health care costs in 1983 continued, however, to grow more rapidly than the overall price index (3.8%) and the gross national product (7.7%). As a consequence, health care expenditures now consume a record 10.8% of GNP.

Combined spending by state, local and federal governments for all health care costs was $148.8 billion (or 41.9%) of the total in 1983 while private parties paid $206.6 billion (or 58.1%) of the total. This was a slightly lower share than governments paid in 1982 and slightly higher than the private parties's proportion in 1982.

The shift continued a trend that began in 1980 and occurred despite slight increases in the federal share of the bill. It results from Medicaid and other cuts that have lowered state and local government's share.

Among the private payers, health insurers paid $110.5 billion or 31.9% of all personal health care expenditures. Patients or their families paid $85 billion or 27% of these expenses.

Medicare and Medicaid expenditures amounted to $91 billion in 1983, up from $83 billion in 1982. The $54 billion of this that went to hospitals was one-third of all payments to hospitals and 12.5% higher than the previous year.

Total national spending for hospital care was $147 billion, up 9.1% from the previous year. Federal officials attributed the lower rates of increase to declining hospital admissions and lengths of stay in both the private sector and Medicare—and not to the Medicare's prospective pricing system which did not affect most hospitals until 1984.

Spending for physician services rose from $62 billion in 1982 to $69 billion in 1983. This represented 19% of all health care spending and was an increase of 11.7% compared with a 12.5% increase in 1982.

Nursing home care consumed $28.8 billion of the total health dollars; dental services $21.8 billion; drugs and medications, $23.7 billion; and medical devices and equipment $6.2 billion.

Third parties, including Medicare, Medicaid and private insurers, financed 73% of all personal health care expenditures in 1983. They paid for 92% of all hospital care, 72% of physician services and 44% of other health care.

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Rate Setting Said to be Cost-Saving

State rate setting programs in four states where Medicare has waived its regular reimbursement rules to participate in the state program are saving Medicare $1 billion a year, according to projections from the Johns Hopkins Center for Hospital Finance and Management.

The findings were announced at a Washington, DC, press conference by a new coalition of groups pushing for expansion of similar rate setting programs to other states. The coalition's immediate interest is in assuring continued Medicare participation in the four currently waivered states and publication of regulations that would permit other states to apply for waivers.

Eleven states (Connecticut, Florida, Maine, Rhode Island, Washington, West Virginia, Wisconsin, Maryland, Massachusetts, New Jersey and New York) have some form of mandatory rate setting apparatus but Medicare participates in only the latter four. The Medicare diagnosis related groups (DRG) prospective pricing system applies in all other states.

Congress specified in the DRG law the conditions under which state systems may be exempted from the federal system and several states—including Connecticut, Maine, West Virginia, Washington, and Wisconsin—are expected to apply for waivers. As many as 16 states are likely to consider rate setting plans next year.

The Administration's failure to issue the waiver regulations some 19 months after passage of the law has tended to confirm rumors that White House budget officers want to squelch these and other waivers in the belief they raise federal costs. A key test will come in late November when a decision is due on a new waiver application from New Jersey.

New Jersey, which pioneered the use of DRGs under a waiver that began in 1980, calculates that continuation of a waiver could save Medicare $126 million over three years. In the first year, however, the waiver is expected to cost Medicare $28 million more than the national scheme would have. New Jersey hospitals have offered to forego one round of Medicare advances to assure that the federal government does not lose money in any year.

Although waiver expirations are not imminent in the other three states, continuation of waivers there was challenged earlier this year by a Federation of American Hospitals study which claimed increased payments in the waivered states were costing hospitals in other states $36 a case. Others have argued that even if rate setting does

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Office of the American Medical Association

hold down overall costs, Medicare participation in such plans may raise federal contributions by forcing Medicare to pick up a share of bad debt it has previously avoided.

Although hospital officials in the waivered states have castigated the FAH study and motives, they are under pressure to show that their systems do work and in particular that Medicare will not lose under these systems.

They have thus teamed up with commercial health insurance industry, groups representing the elderly and organized labor to form a new Coalition of State All-Payers Hospital Payment Systems. Members include hospital and rate setting officials from the four waivered states, Blue Cross plans in the four states, the Health Insurance Association of America, the American Association of Retired Persons, the National Association of Public Hospitals and the AFL-CIO.

The new coalition claims that even Medicare saves money under the rate setting plans. The Hopkins study, whose details are being withheld pending publication, projected that if waivers had been in place in all four states for all of 1982 and 1983, Medicare savings would have amounted to about $1 billion a year.

The group also argues that rate setting plans in which all payers participate represent the best hope of dealing with the problem of how to compensate hospitals for care provided to uninsured and indigent patients.

Groups which oppose a federally-mandated all-payer approach are the FAH, the American Hospital Association, the Blue Cross and Blue Shield Association and the American Medical Association. The AHA does favor the state waiver option, however, and the AMA has suggested that rate setting proposals "be examined at the state level."

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DRGs Inflated, GAO Says

Medicare's diagnosis related groups (DRGs) rates are inflated because the data base used to calculate the rates included excessive payments for respiratory therapy, the General Accounting Office has concluded.

In a study of 33 hospitals that contracted for respiratory therapy services in 1981, GAO concluded that cost reports for 26 of the institutions overstated respiratory therapy costs by an average of 38% and total hospital costs by an average of 1%. Further examination of claims in eight hospitals by medical reviewers indicated that 4.6% of the respiratory therapy services in those hospitals were medically unnecessary.

Because the DRG rates are based on 1981 cost data, the inclusion of excessive payments for respiratory therapy services—which account for about 4% of Medicare payments for inhospital care—resulted in inflated DRG rates, the GAO report said. It advised that Medicare develop programs to audit hospital cost data and utilization "to help assure excessive costs included in the initial DRG rates are perpetuated."

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HHS Says Medicare Costs Could be Cut by Multiple Visits

Medicare should save about $1.3 billion over the next five years if payments for physician visits to patients in hospitals and skilled nursing homes were reduced when the physician had made "multiple visits" in a single trip to the institution.

That is the finding of a study by the Inspector General of the Department of Health and Human Services who wants the department to ask Congress for permission to implement this reimbursement change. The Health Care Financing Administration refused to act on the recommendation but agreed to study it as part of the overall issue of physician reimbursement.

Essentially the IG's recommendation would extend a concept that since 1970 has paid physicians billing for a "multiple visit" at an ICF about $3 per visit less than for a visit to a single patient in the facility.

If the "multiple visit" billing reduction were applied only to patients in skilled nursing facilities, Medicare could save $139 million over five years, the report estimated. Application to hospital visits as well would save another $1.2 billion.

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Hospice Bill Passed

Legislation to increase payments for home care services provided to Medicare hospice patients received final approval by Congress in its waning days.

The bill, which the President has until November 9 to sign or veto, would restore the home care payment to the $53.17 a day the Department of Health and Human Services initially proposed but later lowered to $46.25. The Congressional Budget Office estimates that the just-enacted increase will increase Medicare spending by "no more than $1 million" in fiscal 1985.

The Congressional action followed several studies that found that few hospices were signing up for the Medicare hospice program and that many cited inadequate home care rates as the rationale for nonparticipation.

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President Vetos NIH Authorization Bill

President Reagan this month vetoed a bill that would have made several important changes in the structure and management of the National Institutes of Health (NIH), thus delaying for another session of Congress any plans to create a new arthritis institute, nursing institute, and numerous other small disease commissions.

In a statement accompanying his veto of S 540, the

Health Research Extension Act, the President contended that the bill created unnecessary and expensive new organizations, required overly specific management requirements, and went far beyond its mission by rewriting all relevant statutes of NIH.

President Reagan said his veto will not affect NIH funding for FY 1985, since money to support the institutes was included in another spending bill, already passed and signed.

The structural changes, which were the first major attempt in years to alter the way NIH does business, would have created:

- an Arthritis Institute, to focus increased attention on the joint and connective tissue disorders that afflict 40 million Americans;
- a Nursing Institute, which would have linked nursing research closer to the mainstream of scientific investigation in other health care disciplines; and
- fetal research provisions, including a moratorium on the government's ability to waive risk standards for certain types of fetal research thus restricting experimentation in this area.
- guidelines for the proper care and treatment of animals used in biomedical and behavioral research, giving NIH the authority to revoke funding if a lab failed to meet the guidelines.

A veto had been urged by NIH director James Wyngaarden, M.D., officials at the Department of Health and Human Services, and the AMA.

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Reagan Kills Manpower Bill

Carrying through on an earlier threat, President Reagan has vetoed an omnibus bill reauthorizing health professions assistance, nurse training, the National Health Service Corps and community health centers.

In his veto message, the President said the measure would have "continued and increased obsolete federal subsidies to health professions students" at a time when the "surplus of physicians has reduced the need for federal financial incentives."

The message also noted, however, that a continuing resolution approved by Congress just before adjournment "provides adequate authority for the continuation" of the programs in the vetoed bill. In fact, the President's veto is expected to make little difference to the current operation of the programs which with or without the veto were to be funded at FY 1985 appropriations levels.

The veto will force Congress to reconsider the manpower programs again next year, however, and it signals a new battle to limit federal support of manpower programs and give the White House greater control over their funding.

Congressional committees had anticipated a veto during their later deliberations on the manpower measure and had made several cuts in funding authorizations in an attempt to stave off the veto. Total funding for all the reauthorized programs in fiscal 1985 was about $740 million, with about $158 million of that allocated to health professions assistance. The measure also included a study of Rep. Ron Wyden's (D-OR) proposal to have the Public Health Service give technical assistance to groups that collected and interpreted health care data.

The White House had also sought to replace current categorical grants with an omnibus authorization to be divided up at the discretion of administration officials. This Office of Management and Budget proposal had never been formally introduced as legislation but Reagan cited the continuation of "the rigid and categorical framework" of health professions grants as one reason for his veto. He also claimed that the reauthorization funding levels ($2.4 billion through 1987) were still far in excess of his budget request ($1.7 billion).

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White House Also Nixes Technology Council

In a tersely worded message to Congress, President Reagan warned that he would not request funding for the new Council on Health Care Technology, a quasi-private clearinghouse for technology assessment.

Although Reagan signed S 771, which authorized the Council, he noted "strong objection" to the constitutionality of the group.

Under the bill, passed earlier this month by Congress, the Council would collect information about specific health care technologies, promoting some and discouraging others. It would be composed of members chosen by the federal Department of Health and Human Services and the private National Academy of Sciences, including federal officials, members of the general public, and representatives of the fields of medicine, law, ethics, economics and management.

Reagan contended that the council would mix governmental and non-governmental, executive and legislative elements "in a manner which is inconsistent both with the constitution and with sound government practices."

Because the Council would perform government duties, it is unconstitutional for its members to be selected by a nongovernmental agency, he noted.

The President asked Congress to go back to the drawing board, revamping the structure and function of the Council. Until such remedial legislation, he will refuse to ask for funding in his January budget. However, Congress could override this deferral, if it wished.

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Non A-Non B Hepatitis Virus Found

Food and Drug Administration scientists have identified a third virus of hepatitis. Until now this was called non-

A non-B since it was known that the virus not either hepatitis A of hepatitis B virus. Until now, however, there has been no way to identify it. The new virus turns out to be a member of the retrovirus family. Such agents are now under intensive study because of their potential for effecting subtle but potentially serious changes in the immune system. One such retrovirus has been identified as the cause of the acquired immune deficiency syndrome, for instance, while other play a role in the development of human leukemias. The retrovirses are so-called because they have an enzyme called reverse transcriptase. This enables DNA to be assembled from an RNA template—the reverse of earlier classic thinking which had held that only DNA could make RNA.

The importance of the latest finding is that it will make possible a test to eliminate non-A non-B hepatitis from blood tranfusions. Currently about 90% of post-transfusion hepatitis is caused by this new-found agent.

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Cuts Threaten Medical Education, Congress Finds

Cost-cutting pressures among businesses, health insurers and the federal government are threatening the current method of funding medical education in the U.S. and could lead within a just a few years to a situation in which the number of medical school graduates greatly exceeds the number of residency slots available to them.

This frightening possibility, raised at a Senate Finance health subcommittee hearing, is leading to a reassessment of the way graduate medical education is paid for today. It has led some, including subcommittee chairman Sen. David Durenberger (R-MN), to propose replacement of the present system, which is largely financed through patient care revenues, with an explicit public subsidy for medical education.

Many of those most intimately involved in medical training, including the American Medical Association, the Association of American Medical Colleges and the American Hospital Association, view such explicit federal funding as susceptible to political whim, however. They believe this type of subsidy would lack the stability that at least until recently had characterized the present funding method.

The issue came to the forefront during the development of Medicare's prospective pricing system and a recommendation by a Medicare advisory council calling for the "orderly withdrawal" of Medicare from the financing of medical education.

Durenberger, who plans a series of hearings on medical education, introduced legislation shortly before adjournment to replace the Medicare payment for the direct costs of medical education with a grant program.

At an opening hearing in early October, he said he believes the current reimbursement policies: result in some states' citizens paying to educate physicians who move to other states; may be providing a greater depth of knowledge than necessary; may encourage overproduction of surgeons and hospital-based specialists; can no longer be afforded by Medicare; and will also be rejected by the private sector as competitive plans such as preferred provider organizations steer members away from expensive teaching hospitals.

In view of these concerns, Durenberger predicted, the "direct graduate medical education pass through, as we know it, will be eliminated within two years, and the indirect adjustment for medical education expenses will require refinement." He called for "explicit government policies" to determine "who will take responsibility for graduate medical education and how much will we pay for it."

In defending the current financing arrangement, witnesses generally agreed that patient revenues have provided the dependable financing necessary to assure residents of the continuation of a training program throughout its three to seven year duration. They emphasized that the medical education allowance buys more than the training of health professionals, said it is impossible to completely separate the costs of medical education and patient care, and advised that even a better measurement of severity will not completely explain the higher costs associated with teaching hospitals.

All the witnesses urged that Medicare funding of medical education not be abandoned "precipitously" and both the AMA and the AHA stressed that some Medicare funding will continue to be necessary.

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"Bad Docs" Bill Fails

Legislation to expand the federal government's authority to act against physicians disciplined by state medical boards or by Medicare or Medicaid will have to await action in a new Congress if it is to become law.

Rep. Henson Moore (R-LA) who introduced the measure (HR 5989) in the House had hoped to see it enacted prior to a scheduled October 5 adjournment of this Congress. Moore was able to push the bill through the House Ways and Means Committee, of which he is a member. A plan to take the measure directly to the floor of the House was thwarted, however, when the Energy and Commerce Committee refused to waive its jurisdiction and permit the bill to come up for a vote without action in the Commerce committee.

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Medicare Changes January 1

Medicare's more than 30 million beneficiaries will be required to pay a deductible of $400 each time they are hospitalized next year. The new deductible, which takes effect January 1, is a 12.4% increase over the current $356 deductible.

Other Medicare coinsurance rates based on the deductible will rise accordingly. The premiums the recipients pay for Part B coverage of physician services will also rise—from $14.60 a month to $15.50 a month.

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Congress Forwards HHS Appropriations Bill

Although it exceeds his budget request by some $5 billion, President Reagan is expected to sign a $104.6 billion appropriations measure that includes $79.6 billion for programs within the Department of Health and Human Services. Funding for HHS programs, which will increase by nearly $6 billion, includes:

$410.5 million for the Centers for Disease Control and $5.15 billion for the National Institutes of Health.

- $922.6 billion for the Alcohol, Drug Abuse and Mental Health Administration, including $490 million for the mental health block grant and $196.2 million for mental health research.
- $234.5 million for training of physicians, nurses and other health professionals.
- $75 million for the National Health Service Corps field service and $360 million for community health centers.
- $478 million for the maternal and child health block grant.
- $16.3 billion for federal Medicaid grants to states and $17.9 billion for physician and other services covered under Medicare Part B. Medicare Part A is not included in the appropriations bill because it is funded through Social Security trust funds. Some $2.4 million will be taken from the trust funds to finance the Prospective Payment Assessment Commission.

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Organ Transplant Bill Enacted

With storybook style, Congress came to the rescue of the nation's beleagered organ transplant system, pulling it to its feet with over $31 million in grants and two major task force reports.

It was not without last-minute hesitancy: faced with a deadlock, they deleted controversial provisions that would have paid for cyclosporin and restricted transplant procedures to eligible patients, physicians, and hospitals.

Nonetheless, their agreement—passed by the House on October 3 and the Senate on October 4, then signed by President Reagan later in the month—represents a major effort to close the gap between federal law and new medical technologies.

The bill has four major provisions:

- a report on the safety, efficacy, cost and reimbursement status of the immunosuppressive medications that prevent organ rejection, to be presented to the Department of Health and Human Services within 7 months for further action;
- an analysis of medical centers now performing transplants to determine whether they are under or overabundant, well-distributed around the country, and accessible to the public, to be released to HHS within 12 months for further action;
- $25 million in grants to support the planning, establishment, and expansion of organ procurement organizations, and
- $2 million a year to set up a 3-year national Organ Procurement and Transplantation Network, which would match organ donors and recipients.

Also included is a measure that outlaws the buying and selling of organs, except replenishable tissues such as blood or sperm.

* * * *

Anti-Quack Campaign Launched

A national public information campaign was launched in October to combat the bogus health devices and drugs that cost consumers an estimated $10 billion every year.

More than 4500 advertising agencies and 1000 health care companies have been asked by the Food and Drug Administration to enter an advertising contest to warn the public about the hazards of "miracle" weight reducers, arthritis and cancer cures, baldness remedies, phony sex aids, bust expanders, and fake "fountains" of youth.

The three best submissions will be selected to appear on television, on radio, and in national newspapers and magazines. Contenders are asked to volunteer their efforts, but a $170,000 fund created by 20 drug companies will help offset other expenses.

The contest is supported by the AMA, the American Pharmaceutical Association, and the National Council of Better Business Bureaus.

* * * *

DES Compensation Ruled by Supreme Court

The drug companies that manufactured the drug diethylstilbesterol (DES) must share the cost of compensating victims of their product, according to a state court ruling upheld in October by the U.S. Supreme Court.

The high court justices, without comment, refused on October 1 to hear an appeal by E.R. Squibb and Sons, Inc. of a Wisconsin supreme court ruling that all manufacturers should be held responsible for damages caused by the durg.

The 1,000 victims of DES who have filed suits have been frustrated in their efforts to collect damages, because they cannot prove the origin of drugs taken 20 to 30 years ago.

Rabies Prevention—United States, 1984

CENTERS FOR DISEASE CONTROL, ATLANTA

These revised recommendations of the Immunization Practices Advisory Committee (ACIP) on rabies prevention update the previous recommendations (*MMWR* 1980; 29:65-72, 277-280) to reflect the current status of rabies and antirabies biologics in the United States. For assistance on problems or questions about rabies prophylaxis, call local or state health departments.*

Introduction

Although rabies rarely affects humans in the United States, every year, approximately 25,000 persons receive rabies prophylaxis. Appropriate management of those who may have been exposed to rabies infection depends on the interpretation of the risk of infection and the efficacy and risk of prophylactic treatment. All available methods of systemic prophylactic treatment are complicated by instances of adverse reactions. These are rarely severe. Decisions on management must be made immediately; the longer treatment is postponed, the less likely it is to be effective.

Data on the efficacy of active and passive immunization after rabies exposure have come from both human and animal studies. Evidence from laboratory and field experience in many areas of the world indicates that postexposure prophylaxis combining local wound treatment, vaccine, and rabies immune globulin, is uniformly effective when appropriately used. However, rabies has occasionally developed in humans who had received postexposure antirabies prophylaxis with vaccine alone.

In the United States, rabies in humans has decreased from an average of 22 cases each year from 1946 to 1950 to zero to five cases each year since 1960. The number of rabies cases among domestic animals has decreased similarly. In 1946, more than 8,000 rabies cases were reported among dogs; 153 cases were reported in 1982. Thus, the likelihood of human exposure to rabies in domestic animals has decreased, although bites by dogs and cats continue to be the principal reasons given for antirabies treatments.

The disease in wildlife—especially skunks, foxes, raccoons, and bats—has become more prevalent in recent years, accounting for approximately 85% of all reported cases of animal rabies every year since 1976. Wild animals now constitute the most important potential source of infection for both humans and domestic animals in the United States. Rabies among animals is present throughout the United States; only Hawaii remains consistently rabies-free.

Four of the six rabies fatalities in US citizens occurring between 1980 and 1983 were related to exposure to rabid dogs outside the United States. In much of the world, including most of Asia and all of Africa and Latin America, the dog remains the major source of human exposure.

Rabies Immunizing Products

There are two types of immunizing products: (1) vaccines that induce an active immune response, which requires about seven to ten days to develop but may persist for as long as a year or more, and (2) globulins that provide rapid passive immune protection, which persists for a short period of time, with a half-life of about 21 days. Both types of products should be used concurrently for rabies postexposure prophylaxis.

Vaccines for Use in the United States: Human diploid cell rabies vaccine (HDCV)**: HDCV is an inactivated virus vaccine prepared from fixed rabies virus grown in WI-38 or MRC-5 human diploid cell culture. The vaccine grown on WI-38 cells and developed in the United States is inactivated with tri-n-butyl phosphate and β-propiolactone (Wyeth Laboratories' WYVACR), while that grown in MRC-5 cells and developed in Europe is inactivated with β-propiolactone (Merieux Institute's RABIES VACCINER). Both vaccines are supplied as 1.0 mL, single-dose vials of lyophilized vaccine with accompanying diluent.

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*If these are unavailable, call the Division of Viral Diseases, Center for Infectious Diseases, CDC ([404] 329-3095 during working hours, or [404] 329-2888 nights, weekends, and holidays).

**Official name: Rabies Vaccine: The duck embryo vaccine which was used from 1957 to 1982 is no longer available in the United States.

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Globulins: Rabies Immune Globulin, Human (RIG): RIG (Cutter Laboratories' HYPERABR and Merieux Institutes' IMOGAMR) is antirabies gamma globulin concentrated by cold ethanol fractionation from plasma of hyperimmunized human donors. Rabies neutralizing antibody content is standardized to contain 150 IU/mL. It is supplied in 2-mL (300 IU) and 10-mL (1,500 IU) vials for pediatric and adult use, respectively.

Antirabies Serum, Equine (ARS): ANTIRABIES SERUMR (Sclavo) is a refined, concentrated serum obtained from hyperimmunized horses. Neutralizing antibody content is standardized to contain 1,000 IU per vial. Volume is adjusted by the manufacturer on the basis of antibody potency in each lot. Currently, a 1,000-IU vial contains approximately 5 mL.

Rationale for Choice of Rabies Immunizing Products

Both types of HDCV rabies vaccines are considered equally efficacious and safe when used as indicated on the labels. Only the Merieux Institute vaccine has been evaluated by the intradermal dose/route for preexposure immunization. No data are available on intradermal use with the Wyeth Laboratories vaccine. The RIG is preferred over ARS, because the latter has a much higher risk of adverse reactions.

Vaccines: The effectiveness of rabies vaccines is measured by their ability to protect persons exposed to rabies and to include antibodies to rabies virus. HDCV has been used concurrently with RIG or ARS to treat 45 persons bitten by rabid dogs or wolves in Iran, 31 persons bitten by a variety of rabid animals in Germany, and 511 persons bitten by a variety of rabid animals in the United States. In these studies, no person contracted rabies after receiving HDCV in combination with RIG.

All persons treated with RIG and five 1.0-mL intramuscular doses of HDCV and tested have developed a rabies antibody titer. The definition of a minimally acceptable antibody titer varies between laboratories and is influenced by the type of test conducted. The CDC currently specifies a 1:5 titer by the rapid fluorescent-focus inhibition test (RFFIT) as acceptable. The World Health Organization specifies a titer of 0.5 IU.

Serious adverse reactions associated with rabies vaccines include systemic, anaplylactic, and neuroparalytic reactions. Serious adverse reactions occur at lower rates in the HDCV vaccine than with previously available types of rabies vaccine.

Globulins: Both RIG and ARS are effective; however, ARS causes serum sickness in over 40% of adult recipients. RIG rarely causes adverse reactions and should be the product of choice when available.

Rationale of Treatment

Physicians must evaluate each possible rabies exposure. Local or state public health officials should be consulted if questions arise about the need for prophylaxis.

In the United States, the following factors should be considered before specific antirabies treatment is initiated:

Species of Biting Animal: Carnivorous wild animals (especially skunks, raccoons, foxes coyotes, and bobcats) and bats are the animals most commonly infected with rabies and have caused most of the indigenous cases of human rabies in the United States since 1960. Unless an animal is tested and shown not to be rabid, postexposure prophylaxis should be initiated upon bite or nonbite exposure to the animals. (See definition in "Type of Exposure" below.) If treatment has been initiated and subsequent testing in a competent laboratory shows the exposing animal is not rabid, treatment can be discontinued.

The likelihood that a domestic dog or cat is infected with rabies varies from region to region; hence, the need for postexposure prophylaxis also varies.

Rodents (such as squirrels, hamsters, guinea pigs, gerbils, chipmunks, rats, and mice) and lagomorphs (including rabbits and hares) are rarely found to be infected with rabies and have not been known to cause human rabies in the United States. In these cases, the state or local health department should be consulted before a decision is made to initiate postexposure antirabies prophylaxis.

Circumstances of Biting Incident: An unprovoked attack is more likely than a provoked attack to indicate the animal is rabid. Bites inflicted on a person attempting to feed or handle an apparently healthy animal should generally be regarded as provoked.

Type of Exposure: Rabies is transmitted by introducing the virus into open cuts or wounds in skin or through mucous membranes. The likelihood of rabies infection varies with the nature and extent of exposure. Two categories of exposure should be considered. They are "bite" (any penetration of the skin by teeth) and "nonbite" (scratches, abrasions, open wounds, or mucous membranes contaminated with saliva or other potentially infectious material, such as brain tissue, from a rabid animal). Casual contact, such as petting a rabid animal (without a bite or nonbite exposure as described above), does not constitute an exposure and is not an indication for prophylaxis. There have been two instances of airborne rabies acquired in laboratories and two probable airborne rabies cases acquired in a bat-infested cave in Texas.

The only documented cases of rabies from human-to-human transmission occurred in four patients in the United States and overseas who received corneas transplanted from persons who died of rabies undiagnosed at the time of death. Stringent guidelines for acceptance of donor corneas should reduce this risk.

Bite and nonbite exposures from humans with rabies theoretically could transmit rabies, although no cases of rabies acquired this way have been documented. Each potential exposure to human rabies should be carefully evaluated to minimize unnecessary rabies prophylaxis.

Management of Biting Animals

A healthy domestic dog or cat that bites a person should be confined and observed for ten days and evaluated by a veterinarian at the first sign of illness during confinement or before release. Any illness in the animal should be reported immediately to the local health department. If signs suggestive of rabies develop, the animal should be humanely killed and its head removed and shipped, under refrigeration, for examination by a qualified laboratory designated by the local or state health department. Any stray or unwanted dog or cat that bites a person should be killed immediately and the head submitted, as described above, for rabies examination.

Signs of rabies in wild animals cannot be interpreted reliably; therefore, any wild animal that bites or scratches a person should be killed at once (without unnecessary damage to the head) and the brain submitted, as described above, for examination for evidence of rabies. If the brain is negative by fluorescent-antibody examination for rabies, the saliva can be assumed to contain no virus, and the bitten person need not be treated. If the biting animal is a particularly rare or valuable specimen and the risk of rabies small, consideration may be given to initiating postexposure treatment to the bitten person and delaying killing the animal for rabies testing.

Postexposure Prophylaxis

The essential components of rabies postexposure prophylaxis are local treatment of wounds and immunization, including administration, in most instances, of both globulin and vaccine (Tables 1 and 2).

Local Treatment of Wounds: Immediate and thorough washing of all bite wounds and scratches with soap and water is perhaps the most effective measure for preventing rabies. In experimental animals, simple local wound cleansing has been shown to reduce markedly the likelihood of rabies.

Tetanus prophylaxis and measures to control bacterial infection should be given as indicated.

Immunization: Postexposure antirabies immunization should always include administration of both antibody (preferably RIG) and vaccine, with one exception: persons who have been previously immunized with the recommended preexposure or postexposure regimens with HDCV or who have been immunized with other types of vaccines and have a history of documented adequate rabies antibody titer (see "Rationale for Choice of Rabies Immunizing Products") should receive only vaccine. The combination of globulin and vaccine is recommended for both bite exposures and nonbite exposures (as described under "Rationale of Treatment"), regardless of the interval between exposure and treatment. The sooner treatment is begun after exposure, the better. However, there have been instances in which the decision to begin treatment was made as late as six months or longer after the exposure because of delay in recognition that an exposure had occurred.

HDCV: HDCV is the only type of vaccine currently available in the United States and should be administered in conjunction with RIG at the beginning of postex-

Table 1

RABIES POSTEXPOSURE PROPHYLAXIS GUIDE—*JULY 1984*

The following recommendations are only a guide. In applying them, take into account the animal species involved, the circumstances of the bite of other exposure, the vaccination status of the animal, and presence of rabies in the region. Local or state public health officials should be consulted if questions arise about the need for rabies prophylaxis.

Animal species	*Condition of animal at time of attack*	*Treatment of exposed person**
DOMESTIC		
Dog and cat	Healthy and available for 10 days of observation	None, unless animal develops rabies†
	Rabid or suspected rabid	RIG§ and HDCV
	Unknown (escaped)	Consult public health officials. If treatment is indicated, give RIG§ and HDCV
WILD		
Skunk, bat, fox, coyote, raccoon, bobcat, and other carnivores	Regard as rabid unless proven negative by laboratory tests¶	RIG§ and HDCV
OTHER		
Livestock, rodents, and lagomorphs (rabbits and hares)	Consider individually. Local and state public health officials should be consulted on questions about the need for rabies prophylaxis. Bites of squirrels, hamsters, guinea pigs, gerbils, chipmunks, rats, mice, other rodents, rabbits, and hares almost never call for antirabies prophylaxis.	

* *All bites and wounds should immediately be thoroughly cleansed with soap and water.* If antirabies treatment is indicated, both rabies immune globulin (RIG) and human diploid cell rabies vaccine (HDCV) should be given as soon as possible, *regardless* of the interval from exposure. Local reactions to vaccines are common and do not contraindicate continuing treatment. Discontinue vaccine if fluorescent-antibody tests of the animal are negative.

† During the usual holding period of 10 days, begin treatment with RIG and HDCV at first sign of rabies in a dog or cat that has bitten someone. The symptomatic animal should be killed immediately and tested.

§ If RIG is not available, use antirabies serum, equine (ARS). Do not use more than the recommended dosage.

¶ The animal should be killed and tested as soon as possible. Holding for observation is not recommended.

posure therapy, as described below. In 1977, WHO established a recommendation for six intramuscular doses of HDCV based on studies in Germany and Iran of a regimen of RIG or ARS and six doses of HDCV. When used in this way, the vaccine was safe and effective in protecting 76 persons bitten by proven rabid animals. The vaccine also induced an excellent antibody response in all recipients. Studies conducted by the CDC in the United States have shown that a regimen of one dose of RIG and five doses of HDCV was safe and induced an excellent antibody response in all recipients. Of 511 persons bitten by proven rabid animals and so treated, none developed rabies.

Five 1-mL doses of HDCV should be given intramuscularly (for example, in the deltoid region). Other routes of administration, such as the intradermal route, have not been adequately evaluated for postexposure prophylaxis and should not be used. The first dose should be given as soon as possible after exposure; an additional dose should be given on days 3, 7, 14, and 28 after the first dose. (The WHO currently recommends a sixth dose 90 days after the first dose.) Because the antibody response following the recommended vaccination regimen with HDCV has been so satisfactory, routine postvaccination serologic testing is not recommended. In unusual instances, as when the patient is known to be immunosuppressed, serologic testing is indicated. Contact state health department of the CDC for recommendations.

RIG (or ARS if RIG is not available): RIG is administered only once, at the beginning of antirabies prophylaxis, to provide immediate antibodies until the patient responds to HDCV by active production of antibodies. If RIG was not given when vaccination was begun, it can be given up to the eighth day after the first dose of vaccine was given. From about the eighth day on, RIG is not indicated, since an antibody response to the vaccine is presumed to have occurred. The recommended dose of RIG is 20 IU/kg or approximately 9 IU/lb of body weight. (When ARS must be used, the recommended dose is 40 IU/kg, approximately 18 IU/lb or 1,000 IU/55 lb body weight). If anatomically feasible, up to half the dose of RIG should be thoroughly infiltrated in the area around the wound, the rest should be

Table 2

RABIES IMMUNIZATION—*JUNE 1984*

I. PREEXPOSURE IMMUNIZATION. Preexposure immunization consists of three doses of HDCV, 1.0 ml, IM (i.e., deltoid area), one each on days 0, 7, and 28. (See text for details on use of 0.1 ml HDCV ID as an alternative dose/route.) Administration of routine booster doses of vaccine depends on exposure risk category as noted below. Preexposure immunization of immunosuppressed persons is not recommended.

Criteria for Preexposure Immunization

Risk category	*Nature of risk*	*Typical populations*	*Preexposure regimen*
Continuous	Virus present continuously, often in high concentrations. Aerosol, mucous membrane, bite, or nonbite exposure possible. Specific exposures may go unrecognized.	Rabies research lab workers.* Rabies biologics production workers.	Primary preexposure immunization course. Serology every 6 months. Booster immunization when antibody titer falls below acceptable level.*
Frequent	Exposure usually episodic, with source recognized, but exposure may also be unrecognized. Aerosol, mucous membrane, bite, or nonbite exposure.	Rabies diagnostic lab workers,* spelunkers, veterinarians, and animal control and wildlife workers in rabies epizootic areas.	Primary preexposure immunization course. Booster immunization or serology every 2 years.†
Infrequent (greater than population-at-large)	Exposure nearly always episodic with source recognized. Mucous membrane, bite, or nonbite exposure.	Veterinarians and animal control and wildlife workers in areas of low rabies endemicity. Certain travelers to foreign rabies epizootic areas. Veterinary students.	Primary preexposure immunization course. No routine booster immunization or serology.
Rare (population-at-large)	Exposure always episodic, mucous membrane, or bite with source recognized.	U.S. population-at-large, including individuals in rabies-epizootic areas.	No preexposure immunization.

II. POSTEXPOSURE IMMUNIZATION. All postexposure treatment should begin with immediate thorough cleansing of all wounds with soap and water.

Persons not previously immunized:	RIG, 20 I.U./kg body weight, one half infiltrated at bite site (if possible), remainder IM: 5 doses of HDCV, 1.0 ml IM (i.e., deltoid area), one each on days 0, 3, 7, 14 and 28.
Persons previously immunized§:	Two doses of HDCV, 1.0 ml,IM (i.e., deltoid area), one each on days 0 and 3. RIG should not be administered.

*Judgment of relative risk and extra monitoring of immunization status of laboratory workers is the responsibility of the laboratory supervisor (see U.S. Department of Health and Human Service's *Biosafety in Microbiological and Biomedical Laboratories*, 1984).

†Preexposure booster immunization consists of one dose of HDCV, 1.0 ml/dose, IM (deltoid area). Acceptable antibody level is 1:5 titer (complete inhibition in RFFIT at 1:5 dilution). Boost if titer falls below 1:5.

§Preexposure immunization with HDCV; prior postexposure prophylaxis with HDCV; or persons previously immunized with any other type of rabies vaccine *and* a documented history of positive antibody response to the prior vaccination.

administered intramuscularly. Because RIG may partially suppress active production of antibody, no more than the recommended dose of RIG should be given.

Treatment Outside the United States

If postexposure is begun outside the United States with locally produced biologics, it may be desirable to provide additional treatment when the patient reaches the United States. State health departments should be contacted for specific advice in such cases.

Preexposure Immunization

Preexposure immunization may be offered to persons in high-risk groups, such as veterinarians, animal handlers, certain laboratory workers, and persons spending time (for example, one month or more) in foreign countries where rabies is a constant threat. Persons whose vocational or avocational pursuits bring them into contact with potentially rabid dogs, cats, foxes, skunks, bats, or other species at risk of having rabies should also be considered for preexposure prophylaxis.

Preexposure prophylaxis is given for several reasons. First, it may provide protection to persons with inapparent exposures to rabies. Second, it may protect persons whose postexposure therapy might be expected to be delayed. Finally, although it does not eliminate the need for additional therapy after a rabies exposure, it simplifies therapy by eliminating the need for globulin and decreasing the number of doses of vaccine needed. This is of particular importance for persons at high risk of being exposed in countries where the available rabies immunizing products may carry a higher risk of adverse reactions.

Preexposure immunization does not eliminate the need for prompt postexposure prophylaxis following an exposure; it only reduces the postexposure regimen.

Human Diploid Cell Rabies Vaccine: Three 1.0 mL injections of HDCV should be given intramuscularly (for example, in the deltoid area), one on each of days 0, 7, and 28. In a study in the United States, more than 1,000 persons received HDCV according to this regimen; antibody was demonstrated in the serum samples of all subjects when tested by the RFFIT. Other studies have produced comparable results. Because the antibody response following the recommended vaccination regimen with HDCV has been so satisfactory, routine postvaccination serology is not recommended.

Booster Doses of Vaccine: Persons who work with live rabies virus in research laboratories or vaccine production facilities and are at risk of inapparent exposure should have the rabies antibody titer of their serum determined every six months; booster doses of vaccine should be given, as needed, to maintain an adequate titer (see "Rationale for Choice of Rabies Immunizing Products"). Other laboratory workers, such as those doing rabies diagnostic tests, spelunkers, and those veterinarians, animal control and wildlife officers in areas where animal rabies is epizootic should have boosters every two years or have their serum tested for rabies antibody every two years and, if the titer is inadequate, have a booster dose. Veterinarians and animal control and wildlife officers, if working in areas of low rabies endemicity, do not require routine booster doses of HDCV after completion of primary preexposure immunization (Table 2).

Postexposure Therapy of Previously Immunized Persons: When an immunized person who was vaccinated by the recommended regimen with HDCV or who had previously demonstrated rabies antibody is exposed to rabies, that person should receive two intramuscular doses (1.0 mL each) of HDCV, one immediately and one three days later. RIG should not be given in these cases. If the immune status of a previously vaccinated person who did not receive the recommended HDCV regimen is not known, full primary postexposure antirabies treatment (RIG plus five doses of HDCV) may be necessary. In such cases, if antibody can be demonstrated in a serum sample collected before vaccine is given, treatment can be discontinued after at least two doses of HDCV.

Intradermal Use of HDCV: HDCV produced by the Merieux Institute has been used for preexposure immunization in a regimen of three 0.1 mL doses given intradermally in the lateral aspect of the upper arm over the deltoid area, one dose each on days 0, 7, and 28. Experience gained with over 2,000 persons vaccinated in the United States by the intradermal route has shown that antibody was produced in all recipients, although the mean response was somewhat lower and may be of shorter duration than with comparable intramuscular immunization. Antibody response in some groups vaccinated outside the United States has been found to be inadequate for reasons not yet determined.

Current data provide a sufficient basis to recommend the 0.1 mL intradermal dose/route as an alternative to the 1.0 mL intramuscular dose/route for preexposure immunization in the United States. Postvaccination serology is not necessary following intradermal (or intramuscular) immunization, except for persons suspected of being immunosuppressed. The manufacturer has not yet met the packaging and labeling requirements necessary to obtain approval by the US Food and Drug Administration for the intradermal route. Since the 1.0-mL vial presently available is intended for intramuscular use and contains no preservatives, the reconstituted vaccine must be used immediately. Data on intradermal immunization are not available for Wyeth Laboratories' vaccine, and it should not be used for intradermal vaccination.

Accidental Inoculation With Modified Live Rabies Virus

Persons may be accidentally exposed to attenuated rabies virus while administering modified live rabies virus (MLV) vaccines to animals. While there have been no reported human rabies cases resulting from exposure to needlesticks or sprays with licensed MLV vaccines, vaccine-induced rabies has been observed in animals given MLV vaccines. Absolute assurance of a lack of risk for humans, therefore, cannot be given. The best evidence for a low risk, however, is the absence of recognized cases of vaccine-associated disease in humans despite frequent accidental exposures.

Currently available MLV animal vaccines are made with one of two attenuated strains of rabies virus: high egg passage (HEP) Flury strain or Street Alabama Dufferin (SAD) strain. The HEP Flury and SAD virus strains have been used in animal vaccines for over ten years without evidence of associated disease in humans; therefore, postexposure treatment is not recommended following exposure to these types of vaccine by needlesticks or sprays.

Because the data are insufficient to assess the true risk associated with any of the MLV vaccines, preexposure immunization, and periodic boosters are recommended for all persons dealing with potentially rabid animals or frequently handling animal rabies vaccines.

Adverse Reactions

Human Diploid Cell Rabies Vaccine: Reactions after vaccination with HDCV are less common than with previously available vaccines. In a study using five doses of HDCV, local reactions, such as pain, erythema, and swelling or itching at the injection site, were reported in about 25% of recipients of HDCV, and mild systemic reactions, such as headache, nausea, abdominal pain, muscle aches, and dizziness were reported in about 20% of recipients. Two cases of neurologic illness resembling Guillain-Barré syndrome that resolved without sequelae in 12 weeks, and a focal subacute central nervous system disorder temporally associated with HDCV vaccine, have been reported.

Recently, a significant increase has been noted in "immune complex-like" reactions in persons receiving booster doses of HDCV. The illness, characterized by onset two to 21 days postbooster, presents with a generalized urticaria and may also include arthralgia, arthritis, angioedema, nausea, vomiting, fever, and malaise. In no cases were the illnesses life-threatening. Preliminary data suggest this "immune complex-like " illness may occur in up to 6% of persons receiving booster vaccines and much less frequently in persons receiving primary immunization. Additional experience with this vaccine is needed to define more clearly the risk of these adverse reactions.

Vaccines in Other Countries: Many developing countries use inactivated nerve tissue vaccines (NTV) or inactivated suckling mouse brain vaccine (SMBV). NTV is reported to provoke neuroparalytic reactions at a rate of about 1/2,000 vaccinees; the rate for SMBV is about 1/8,000.

Rabies Immune Globulin, Human: Local pain and low-grade fever may follow receipt of RIG. Although not reported specifically for RIG, angioneurotic edema, nephrotic syndrome, and anaphylaxis have been reported after injection of immune serum globulin (ISG). These reactions occur so rarely that the causal relationship between ISG and these reactions is not clear.

Antirabies Serum, Equine: ARS produces serum sickness in at least 40% of adult recipients; reaction rates for children are lower. Anaphylactic reactions may occur. When RIG is not available, and ARS must be used, the patient should be tested for sensitivity to equine serum. (See package circular for details.)

Because adverse reactions are associated more frequently with ARS than with RIG, and ARS might sensitize recipients to equine protein, ARS should be used only when RIG cannot be obtained.

Management of Adverse Reactions: Once initiated, rabies prophylaxis should not be interrupted or discontinued because of local or mild systemic adverse reactions to rabies vaccine. Usually such reactions can be successfully managed with antiinflammatory and antipyretic agents (aspirin, for example).

When a person with a history of hypersensitivity must be given rabies vaccines, antihistamines may be given; epinephrine should be readily available to counteract anaphylactic reactions, and the person should be carefully observed immediately after immunization.

Serious systemic anaphylactic or neuroparalytic reactions occurring during the administration of rabies vaccines pose a serious dilemma for the attending physician. A patient's risk of developing rabies must be carefully considered before deciding to discontinue vaccination. Moreover, the use of corticosteroids to treat life-threatening neuroparalytic reactions carries the risk of inhibiting the development of active immunity to rabies. It is especially important in these cases that the serum of the patient be tested for rabies antibodies. Advice and assistance on the management of serious adverse reactions in persons receiving rabies vaccines may be sought from the state health department or the CDC.

All serious systemic neuroparalytic or anaphylactic reactions to a rabies vaccine should be immediately reported to the state health department or the Division of Viral Diseases, Center for Infectious Diseases, CDC ([404] 329-3095 during working hours, or [404] 329-2888 at other times).

Precautions and Contraindications

Immunosuppression: Corticosteroids, other immunosuppressive agents, and immunosuppressive illnesses can interfere with the development of active immunity and predispose the patient to developing rabies. Immunosuppressive agents should not be administered during postexposure therapy, unless essential for the treatment of other conditions. When rabies postexposure prophylaxis is administered to persons receiving steroids or other immunosuppressive therapy, it is especially important that serum be tested for rabies antibody to ensure that an adequate response has developed.

Pregnancy: Because of the potential consequences of inadequately treated rabies exposure and limited data that indicate that fetal abnormalities have not been associated with rabies vaccination, pregnancy is not considered a contraindication to postexposure prophylaxis. If there is substantial risk of exposure to rabies, preexposure prophylaxis may also be indicated during pregnancy.

Allergies: Persons with histories of hypersensitivity should be given rabies vaccines with caution. When a patient with a history suggesting hypersensitivity to HDCV must be given that vaccine, antihistamines can be given; epinephrine should be readily available to counteract anaphylactic reactions, and the person should be carefully observed.

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Causes Of Malpractice Claims By Allegation

1979 – 1983

This data provides an overview of medical malpractice claims against physicians insured by The St. Paul and the average cost of those claims. The top 12 allegations account for almost half of the total claims filed during the five-year period from 1979 through 1983. The figures are useful for physicians and hospitals as a basis for claims prevention programs.

ALLEGATION	NUMBER OF CLAIMS	PERCENT OF CLAIMS	AVERAGE COST
1) SURGERY–POSTOPERATIVE COMPLICATION	2,456	12.0%	$27,792
2) IMPROPER TREATMENT–BIRTH RELATED	1,103	5.4	70,997
3) SURGERY–INADVERTENT ACT	1,012	4.9	27,460
4) FAILURE TO DIAGNOSE–FRACTURE OR DISLOCATION	895	4.4	17,305
5) FAILURE TO DIAGNOSE–CANCER	692	3.4	41,883
6) SURGERY–INAPPROPRIATE PROCEDURE	666	3.2	28,263
7) IMPROPER TREATMENT–FRACTURE OR DISLOCATION	661	3.2	19,528
8) IMPROPER TREATMENT–LACK OF SUPERVISION	570	2.8	20,523
9) IMPROPER TREATMENT–DRUG SIDE EFFECT	568	2.8	29,989
10) FAILURE TO DIAGNOSE–PREGNANCY PROBLEMS	482	2.3	30,585
11) IMPROPER TREATMENT–INFECTION	480	2.3	16,669
12) IMPROPER TREATMENT–DURING EXAMINATION	470	2.3	16,704
TOTAL	10,055	49.0%	

–*Malpractice Digest*, March 1984

COMMITTEE SERVICE QUESTIONNAIRE
Connecticut State Medical Society

Early in 1985 the Councilors from the eight constituent county medical associations assume the responsibility of selecting members of the Society to participate in the various activities of the Society listed below. In making these selections it is of importance to choose physicians who are not only willing and able to serve but also who are known to have an interest in the work of the group to which they may be assigned. In order to enable this office to furnish the Councilors with a compilation of those who desire to be considered for committee service, all members are asked to indicate by number in order of preference (not more than three) opposite your choice in the questionnaire below and return same to the:

Executive Director's Office
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Your cooperation will be appreciated.

Medical Education

☐ Committee on Continuing Medical Education
☐ Committee on Program of the Scientific Assembly

Medical Economics

☐ Committee on Insurance
☐ Committee on Professional Liability
☐ Committee on Third Party Payments

Professional Relations

☐ Judicial Committee

Public Affairs and Communications

☐ Editorial Committee of "Connecticut Medicine"
☐ Committee on Legislation
☐ Committee on Public Affairs

Scientific and Socio-Environmental Medicine

☐ Committee on Emergency Medical Services
☐ Cancer Coordinating Committee
☐ Committee on Drug Abuse Educational Programs
☐ Committee on Maternal Morbidity and Mortality
☐ Committee on Medical Aspects of Sports
☐ Committee on Mental Health
☐ Committee on Organ and Tissue Transfers
☐ Committee to Study Perinatal Morbidity and Mortality
☐ Committee on Public Health
☐ Committee on Statewide Medical Planning

Representatives and Advisors

☐ Committee on Allied Medical Services
☐ Committee on Hospitals
☐ Committee on Cooperation with the Medical Schools of Connecticut
☐ Liaison Committee with Connecticut Pharmaceutical Association
☐ Liaison Committee with State Department of Income Maintenance
☐ Representatives to Connecticut Advisory School Health Council
☐ Delegates to Connecticut Public Health Association, Inc.
☐ Delegates to Connecticut Nutrition Council
☐ Delegates to Council of New England State Medical Societies

Please Return by January 10, 1985

Signed: ______________________________ M.D.
(Please Print)

Office Address: ______________________________

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The President's Page

The Apologists

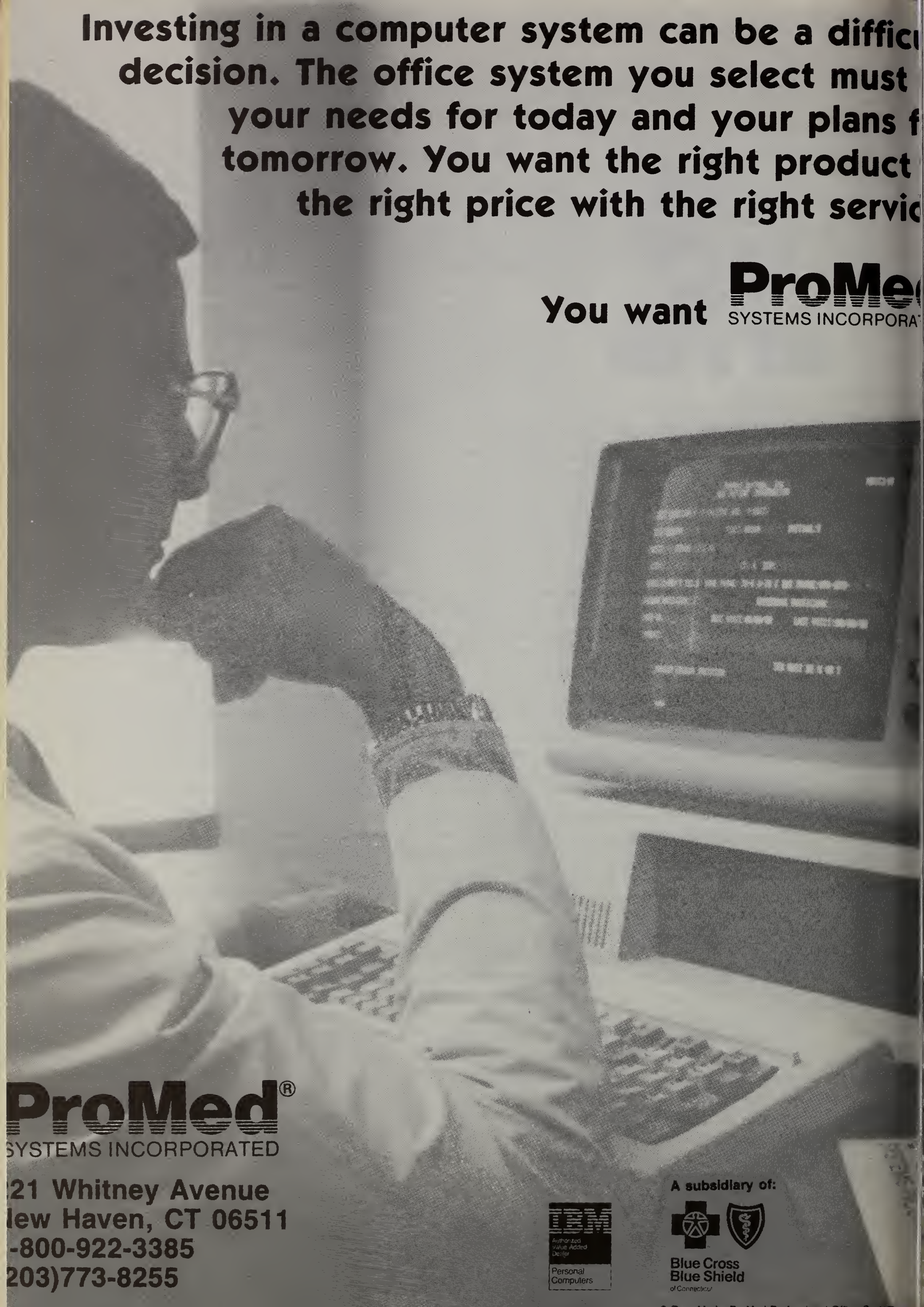
The recent flap over the Acceptance/Non-acceptance of assignment regarding Medicare beneficiaries has led me to ponder the actions which various branches of organized medicine have taken since my early involvement in medical politics. The reactionary responses against medicare in the 1960's are most memorable. As a result of the stance taken at that time, organized medicine lost not only the support of many citizens, including the elderly, but of legislators as well as physicians nationwide and, because of this action, a significant percentage of doctors drifted away from the AMA and their own state medical societies. These losses have been difficult to recoup. In spite of the opposition of organized medicine, this legislation has proven to be a boon not only to the care of the elderly and disabled but also to physician's incomes.

As health care costs grew, the profession seemed to go to the opposite extreme and adopt the philosophy that regardless of the merits of a rule or law, physicians will cooperate. We took the stance, that if we did not agree to cooperate, then someone else would step in and do an ill-defined "something" to us. Thus began an era of teamwork, aided and abetted by physicians who operated under the illusion that by cooperating we would some how turn out to be the "good guys." As a result of this we established PSRO's which failed in their expectations both on a local and national level; we formed panels for second opinions and installed hot line telephones, yet, after three months in Hartford County, there were less than a handful of calls; we have cooperated extensively with the State Department of Income Maintenance, have established utilization review committees, have promoted HMO/IPA organizations and have been willing to go to any lengths to appease third party payors, both public or private.

In spite of all this cooperation, physicians continue to be painted as the "bad guys" who are responsible for ever increasing health care costs. Because of the image which has been created, physicians appear to apologize more and more for their behavior and rush into accepting many poorly planned and formulated schemes promulgated by payors. Why doesn't anyone take the attorney or small businessman to task because he owns a fancy car or vacation home? Yet, the average doctor is a prime target for this criticism. Little attention is paid to the fact that the average doctor works longer hours, charges reasonable fees and maintains a conservative life style and consequently deserves some of the fruits of his labors. It has always been easier to find a scapegoat which, in health care, happens to be the physician, rather than accept the fact that the payors cannot live up to the promises made to their clients, our patients, namely, the best medical care which is available to everyone.

The medicare assignment fiasco has created much concern among doctors. The threat of printing names of doctors in a book to be distributed to medicare recipients has caused many of our members to wonder whether this action will affect their practices and income. I would venture to predict that this action like many which preceded it will have little if any impact on the average doctor or his practice. Patients choose physicians rarely, if ever, by costs but rather by reputation and direct physician referral. I can't imagine any of my medicare patients going to another surgeon because his fees might be lower than mine. The elderly are interested in quality care and contrary to recent pronouncements are willing and able to pay for it. I also have faith in the ultimate empathy that doctors have for their patients and feel that very few would be unwilling to adjust their fees to the ability of the patient to pay. We must continue to do whatever is best for our patients regardless of outside interference whose only thrust is concerned with cost. There is no necessity to apologize for our actions.

Joseph S. Sadowski, M.D.
President



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Reflections from the Dean's Office

Common Foundations

ROBERT U. MASSEY, M.D.

In their introduction to the Report on the General Professional Education of the Physician and College Preparation for Medicine,[1] the Panel affirmed "that all physicians, regardless of specialty, require a common foundation of knowledge, skills, values, and attitudes."

Later, they asserted that "medical faculties should emphasize the acquisition and development of skills, values, and attitudes by students to the same extent that they do their acquisition of knowledge."

And again the panel addressed the matter of values: admission committees were advised to "make final selection decisions using criteria that appraise students' abilities to learn independently, to acquire critical analytical skills, to develop values and attitudes essential for members of a caring profession —."

Medical educators in all of the nation's 127 medical schools will be measuring their teaching and educational programs against the conclusions and the recommendations of the GPEP Report, "Physicians for the Twenty-First Century." Mostly they will say that the report offers little that is new, nothing they have not already thought of and talked about, and certainly little that is controversial. That is the way with committee reports. That is why the Flexner Report of 74 years ago makes for such entertaining reading: it was written by one man.

Yet there is something new. Values are not mentioned in the Coggeshall Report of 1965, even though some change in public values is implied by noting the rising health expectations during the decades following World War II. In the five recommendations of the Millis Report of 1966, there is no talk of values, although knowledge and skill are said to be insufficient without "continuing and comprehensive patient responsibility." The Carnegie Commission Report of 1970 makes no mention of values in its 16 "major themes," or in its recommendations for the future of health manpower education.

We have come through and are perhaps now emerging from a period in which one of the aims of primary and secondary education has been to teach reading and writing while remaining value free and culturally neutral—maybe understandable in a heterogenous society like ours, but no good for transmitting the common cultural and ethical values of a civilization from one generation to the next, no good for general education.

A profession, as well as a society, remains an identifiable entity by reason of its shared knowledge and common values. Without the stories and legends, the ideals, and the rules of good behavior, there will be no peace in the family or the city, no abiding social order, and no committed profession. Without common traditions, accepted authority, an explicit and implicit ethical code, even ordinary discourse becomes sterile, communication turns to babel; words expressing values come to mean anything the speaker chooses and become therefore meaningless unless there is a "common foundation of knowledge, skills, values, and attitudes."

In the past, perhaps values were less often mentioned because more often shared; we assumed a more or less common heritage. Even in our pluralistic society there used to be an accepted literary canon in which our ideas of the good, the true, and the beautiful were imbedded. Fifty years of value neutrality in education have left us with a generation whose values, even though shared in part, have remained largely unspoken, and therefore garbled in the transmission.

The GPEP Report includes recommendations on many aspects of education, both general and professional; that it is concerned so explicitly with values and attitudes may be new in our time, but clearly places it alongside the many other calls for educational reform.

Our students may grapple with the tough issues of medical ethics, and our medical humanists may help them to learn some principles of ethical reasoning. They might even agree on some broad definition of a moral society, but without a shared literary tradition, they will not easily come together on the description of a virtuous individual; the best we can do in medical school then is to set an example, to "insist that we are here, not to get all we can out of the life about us, but to see how much we can add to it."[2]

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1. Physicians for the Twenty-First Century, The GPEP Report, Association of American Medical Colleges, Washington, DC, 1984.
2. Osler W: The General Practitioner, in The Student Life, Verney RE, editor, ER Livingstone Ltd, Edinburgh and London, p 100, 1960.

ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

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Editorials

Organ Transplantation

The recent Tenth International Congress of the Transplantation Society emphasized the intense activity ongoing in basic and clinical transplantation. With the availability of Cyclosporin A the success rate for all transplanted organs has increased. This makes it practical now to replace the heart or liver of a patient who has end stage disease. However, Cyclosporin A represents only another step in the search for more selective immunosuppressive therapy. Other Cyclosporin derivatives currently being examined seem to have the same immunosuppressive properties but lack Cyclosporin A's toxicity.

The immune response which is activated by an organ allograft involves a variety of cells (macrophages, helper T cells, Cytotoxic T cells, suppressor cells, NK cells, B cells etc) that release a number of molecules (lymphokines) that direct and intensify a rejection episode. It is well established that the immune system has endogenous down-regulator mechanisms that serve to protect the organism from unconstrained auto-immune responses and to establish tolerance to self antigens. These functions are largely performed by suppressor T lymphocytes and the soluble factors that they elaborate.

Cyclosporin has been shown to have a relative sparing effect on T suppressor cells which in turn renders the host "tolerant" toward allografted tissues. For maximal effect it requires the concomitant use of steroids. Monoclonal antibodies are also being used, not only for the identification and characterization of cell subsets in rejection, but also to treat rejection. The mode of treatment appears quite effective at reversing rejection but must be combined with other immunosuppressants, such as Cyclosporin, to prevent recurrent rejection.

While considerable progress has been made toward achieving pharmacological immunosuppression, specificity is lacking and the patient is therefore often rendered susceptible to viral, fungal or bacterial infections. Organ transplantation is constantly striving to achieve a balance between rejection and infection or between too little or too much immunosuppression. With improvements in this balance, transplantation can more safely be offered to higher risk patients.

It is important to increase the numbers of patients that receive renal transplants since the numbers of patients being added to the dialysis pool are increasing each year. Transplantation has been found to be cost effective for renal transplants versus dialysis. A patient with end stage renal disease can make this choice between dialysis and transplantation. For the patient with end stage hepatic, cardiac or pulmonary failure no such choice exists. Replacement with a new organ offers the only chance of survival for these patients. At the same time, survival is dependent upon immediate function of the graft since no temporary support system is available as is provided by dialysis for the renal transplant recipient. Transplantation of extra-renal organs can also be cost effective since terminal hospitalization of these patients is often expensive and provides no hope of recovery.

The availability of transplantation, unlike other areas of medicine, often requires the generosity of strangers in donating adequate numbers of healthy organs. Although the number of organs has increased, the majority of potential donor organs are not recovered. Multiple factors contribute to non-donation—religious beliefs and mores, family preferences and medical staff indifference. The availability of highly skilled organ procurement coordinators now minimizes the time commitment required of members of the primary health team to maintain a potential donor. The response from families consenting to donation has been overwhelmingly positive. The opportunity to provide health or life to another person often lessens the grief resulting from the death of a loved one.

A better understanding of the mechanisms of immunity will have a profound effect, not only by improving the results of organ transplantation, but by allowing a better understanding of autoimmune disease and the immuno-

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depressed states resulting from a variety of conditions, such as the traumatized or post surgical patient or the individual with a malignant tumor.

M. Wayne Flye, M.D., Ph.D.

Professor of Surgery and Director of the Division of Organ Transplantation and Immunobiology, Yale University School of Medicine, New Haven, CT.

AMA Hospital Medical Staff Section

One look at the composition of the AMA House of Delegates quickly reveals disproportionate representation of physician interests. On June 13, 1982, the AMA Board of Trustees appointed a committee, chaired by Dr. Thomas C. Peebles, a practicing Pediatrician affiliated with Massachusetts General Hospital to study measures to remedy this inequity. His supporting cast was chosen to gather information from multiple disciplines and interests. Their study produced a recommendation accepted by the parent board and resulted in the formation of a new section, named AMA-Hospital Medical Staff Section. At the first meeting held in Chicago, a rather smooth and orderly election of officers and agenda for business at hand were conducted prior to the official meeting of the House of Delegates. Subsequently, two additional meetings have been held, each preceding the House of Delegates semi-annual and annual meetings. Successive sessions have provided in depth exchange of ideas, discussions of many controversial problems and on occasion heated debates about conflicting interests and directions to be taken by American Medicine.

Guest speakers continually reminded the section that some of the most urgent problems facing medicine today are the accessibility, sophistication, utilization and perhaps most importantly, the cost of medical care. In this climate sincere attempts are being made to end some of the confrontational attitudes that have surfaced with growing competition for medical care remuneration. The President of the American Hospital Association assured the members that it would be most unwise for hospitals to become competitors of physicians for patients. Other speakers outlined the growth and diversity of alternative methods of funding and providing medical care (i.e. HMO's, PPO's and large free standing clinics). Business leaders have aggressively pursued programs to contain costs by demanding that workers share in the initial responsibilities by deductibles and pay backs for unexpended resources. Rapid changes are occurring and new problems keep arising. In discussions with other participants, it is becoming abundantly clear that there are problems unique to geographical areas and require purely local solution.

At our second annual meeting in Chicago a total of 766 registrants with 573 voting delegates learned that the section has requested representation on the JCAH. We were told that expansion of DRG's may lead to universal capitation. Five speakers addressed the delegates on the first day of the meeting. B.J. Anderson, J.D. Associate Counsel of the AMA Office of General Council discussed the medical staff's responsibilities to patients, individual staff members and the hospital. She emphasized the continued need for co-operation rather than confrontation and pointed out that a good working relationship was most important for the survival of both. Michael Bromberg, J.D. Executive Director of the Federation of American Hospitals discussed the trends in multi-hospital health care systems and predicted growing competition among physicians and rate controls at state levels. One aspect of care remains uncertain-quality control of care.

Louis A. Orsini, Vice President of the Consensus and Professional Relations Division of the Health Insurance of America spoke on provider incentive systems.

The speech entitled "Views From The Private Section" outlined historically the establishment of Health Task Forces in the 1970's to the present. Two hundred CEO's of large corporations have joined forces to address the major issues facing them with respect to health care. They have organized task forces to study and concentrate efforts on six areas.

1. Data base on claims (i.e. frequency, short term, long term illness, etc.).
2. Benefit Package and Cost Effectiveness.
3. Provision of health care, accident, illness, etc.
4. Review and evaluate programs for prudent use.
5. Corporate executives to serve on boards of hospitals.
6. Participate in coalition of health care organization.

In 1983 a survey revealed that 50% of firms participated in cost sharing.

Finally, the AMA House of Delegates approved of a number of resolutions related to the organization and operation of the medical staff:

1. Supported the medical staff's authority to approve or disapprove all amendments to medical staff by-laws.
2. Supported the idea that the hospital governing boards cannot unilaterally change medical staff by-laws.
3. Asked the AMA to prepare and distribute a document on the legal status of medical staffs.
4. Encouraged hospitals and medical staffs to make all medical staff by-laws available to physicians.
5. Directed the AMA to oppose any regulation that would mandate voting privileges for non-physician members of the medical staff.
6. Recommended that medical staffs develop by-law provisions that affirm the binding effect of medical staff by-laws on the hospital governing board and the medical staff.

Your Connecticut representatives, though few in number, have attended faithfully and participated in all aspects of the meeting (i.e. candidates for positions, discussions regarding issues and service on committees of the House). Two members of the state council were interested enough to attend a full afternoon session with the Connecticut Delegation (Drs. Frank Abbott and Stuart Petrie). The Chicago office is anxious for all the states to develop sections within each state so that more effective local action will follow the national meeting. Such a resolution has been sent to the Council of the Connecticut State Medical Society, initiated by Dr. Nicholas Spinelli of Bridgeport Hospital and myself.

It has been my observation that states interested in working at the AMA House of Delegates level have attracted more enthusiasm in their states for participation in the medical staff section. In Connecticut, there is a small core of physicians who remain loyal to their fellow physicians and give of their time unselfishly. We now have two medical schools in the state and the opening of the second did nothing to bolster support for the work of the state medical society. Too many of our full time people remain aloof and out of touch with the everyday problems of medicine as it is practiced throughout the state. This tends to create barriers of misunderstanding and widens the 'Town-Gown' gap. If the new Hospital Medical Staff section is effective in producing a climate of free exchange and co-operation, it will have justified its creation.

Michael A. Dean, M.D.
St. Vincent's Medical Center Representative
to the AMA HMSS

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

To the Editor: Economist Freemon Jones makes some frightening assumptions in his article, "Measuring Economic Damages in Wrongful Death," in the September, 1984 issue of the *Journal.*

"Malpractice awards (are) reaching truly astronomical levels," he writes. "Like it or not, this condition is here to stay. There is no way the situation can be reversed since even legislation cannot stop the tide." He then goes on to conclude that physicians should all have liability insurance equal to their net worth, as if this would prevent loss of these assets in a liability suit.

I have no quarrel with the fact that awards are astronomical, or with the calculations made in the article as to the possible future estate of a physician who had an untimely death early in his career. My horror is directed at the assumption that there is no legislation to stem the tide. Ours is a system of laws based on justice for all, and it is clear that this system has not been working well. Not only *can* our tort system be changed, it *must* be changed!

The case in point is a good example of the injustice of our current system. The young physician who was killed in a plane accident could have built up an estate worth $15,000,000, with a present value which was calculated at $6,000,000. The article assumes that since this was a "wrongful death" that the estate should be awarded this amount. A corollary assumption is that since his wife and daughter who were killed in the same accident were not earning income, there are no "economic damages" to be sought.

But the fact is, that this money was never *earned.* The potential was clearly there, but someone else will do the work, and someone else will earn the income. There is no guarantee that this physician would not have retired early, or committed suicide, for that matter. Should society pay for $6,000,000 worth of work that was never done? In the long run, it is the public that pays this bill, a public which has not done any harm but will have to pay increased insurance premiums and will pay higher costs for products that in turn are covered by higher liability insurance rates.

And who gets all this money? The man's wife and daughter were killed along with him. He presumably has life insurance to cover any other children that may be living. But should they inherit millions of dollars for work that was never done? Even worse, there may be no living offspring, in which case all the other living relatives can scramble for the pile of money they never deserved.

And then there is the attorney for the estate! Since there is a suit involved for the "wrongful death," there is a 30-40% contingency fee to be "earned." $2,000,000 to be won with a few weeks of paper work, money that would have taken the young physician a decade to earn if he was able to keep up a 60-hour work week.

The fact that the public tolerates such unfairness is appalling. But because our society is able to address injustice through a democratic legislative process, I do not feel that we are as helpless as Mr. Jones suggests we are.

Physicians must help educate the legislature and the public about the injustices of the tort system as it applies to medical liability. The cost to society has been staggering, and the profits made by a few are enormous.

To institute a change, we must organize specifically around this issue, which has become a terrifying burden for every practitioner in the U.S.

David B. Bingham, M.D.
Norwich, CT
President, Conn-TORTS
(Conn-TORTS is a private non-profit organization of physicians dedicated to research, write, and eventually lobby for medical liability tort reform in the State of Connecticut.)

HUGE DAMAGE AWARDS ENDANGER HEALTH CARE

To the Editor: The article by the economist J. Fremon Jones (in the September issue of *Connecticut Medicine*) on measuring economic damages in tort cases demonstrates in a nutshell what is wrong with our strangling system of medical liability litigation.

There is something grotesque in the method used by tort attorneys' economists to determine damages. Jones relates the tale of one Dr. Williams who perished with his family in the crash of a small plane. Beneficiaries of his estate are to receive unexpected windfalls of astronomical sums.

Flying a small, private plane carries some risks not usually covered by life insurance policies without a special surcharge. If people close to Dr. Williams had to be provided for in the event of accident, he should have—and probably had—arranged for such coverage. He could have been killed by windshear or an unexpected downdraft, on this or any other of his small-craft flights.

In calculating Dr. Williams' lifetime earning capacity there is an overzealous application of economics which has the trappings of precision. But there is a seamy side to it. Mr. Jones and his law firm are not disinterested parties in the calculation: they happily accept 40% of the victim's calculated lifetime earnings.

Unfortunately, this type of highly lucrative litigation, when applied to medical practice, proves not protective but destructive of Public Health. It has reached this critical stage in Florida where physicians in some fields have to start practicing with liability premiums of $1,000 per week. The malaise is creeping across the nation and a Public Health crisis is waiting in the wings.

For example, in recent years, many manufacturers ceased production of childhood vaccines because of unrealistically high litigation awards, even when the vaccines were perfect. In the last few years the cost of the D.P.T. vaccine has increased tenfold and in the case of many essential vaccines administered to all children, only a single manufacturer remains in the U.S. For instance, the measles vaccine, made by six companies 20 years ago, is now manufactured by only one. So are the vaccines for the mumps, the German measles and the Salk vaccine. Other manufacturers dropped out because of the high cost of litigation. Local vaccine shortages have already started to develop and are causing justifiable alarm.

If serious health consequences were to arise, I believe that tort attorneys as a group would be responsible. But that's not their concern. Their interest lies in huge awards, not Public Health.

Hans H. Neumann, M.D.
Wilton, CT

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Medical Record Regulations Finalized

After a year-long process, the State Department of Health Services has finalized regulations to define: 1) the content of a medical record and 2) a retention schedule.

Medical Records—Definition, Purpose (Section 19a-14-40):

The purpose of a medical record is to provide a vehicle for: documenting actions taken in patient management; documenting patient progress; providing meaningful medical information to other practitioners should the patient transfer to a new provider or should the provider be unavailable for some reason. A medical record shall include, but not be limited to, information sufficient to justify any diagnosis and treatment rendered, dates of treatment, actions taken by non-licensed persons when ordered or authorized by the provider; doctors' orders, nurses notes and charts, birth certificate worksheets, and any other diagnostic data or documents specified in the rules and regulations. All entries must be signed by the person responsible for them.

Retention Schedule (Section 19a-14-42):

Unless specified otherwise herein, all parts of a medical record shall be retained for a period of seven (7) years from the last date of treatment, or, upon the death of the patient, for three (3) years.

(a) **Pathology Slides, EEG and ECG Tracings** must each be kept for seven (7) years. If an ECG is taken and the results are unchanged from a previous ECG, then only the most recent results need be retained. Reports on each of these must be kept for the duration of the medical record.

(b) **Lab Reports and PKU Reports** must be kept for at least five (5) years. Only positive (abnormal) lab results need be retained.

(c) **X-Ray Films** must be kept for three (3) years.

Additionally, the regulations specify the use of a "public notice" as a way for retiring physicians to notify patients of discontinuance of their practice.

Discontinuance of Practice (Section 19a-14-44):

Upon the death or retirement of a practitioner, it shall be the responsibility of the practitioner or surviving responsible relative or executor to inform patients. This must be done by placing a notice in a daily local newspaper published in the community which is the prime locus of the practice. This notice shall be no less than two columns wide and no less than two inches in height. The notice shall appear twice, seven days apart. In addition, an individual letter is to be sent to each patient seen within the three years preceding the date of discontinuance of the practice. Medical records of all patients must be retained for at least sixty days following both the public and private notice to patients.

Current Law:

Existing law (P.L. 83-413) requires a practitioner (physician) to furnish to a patient upon written request and at a reasonable cost a copy of the patient's health record including x-rays, copies of laboratory reports, prescriptions and other information used in assessing the patient's health condition. A practitioner is also required to supply to a patient, upon request, complete and current information in his possession regarding the patient's diagnosis, treatment and prognosis.

Record Released to Another Provider

A practitioner is required to furnish a copy of the patient's health record to another practitioner upon the written request of the patient. The patient is responsible for the cost of furnishing the information.

Withholding Access

A practitioner is permitted to withhold information detrimental to the patient's physical or mental health, or likely to cause the patient to harm himself or another.

When a practitioner withholds information considered detrimental to the patient, he would be permitted to supply the information to an appropriate third party who could release it to the patient.

Persons aggrieved by a physician's decision to withhold information may petition the Supreme Court for an order requiring disclosure. The court, after having a review in the judge's chambers, would issue the request order unless it determined that disclosure would be detrimental to the health of the person or is likely to cause the person to harm himself or another.

Unpaid Accounts

A physician who formerly treated a patient should not refuse for any reason to make records of that patient promptly available on request to another physician presently treating the patient. Medical reports should not be withheld because of an unpaid bill for medical services.

FROM THE EXECUTIVE DIRECTOR'S OFFICE

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Robert J. Brunell
Assistant Executive Director
Scientific Activities

Richard J. Fiorentino
Coordinator
Special Services

Council Meeting

Wednesday, October 17, 1984

Attendance

Present in addition to the Chairman, Dr. G.W. Van Syckle and the Vice-Chairman, Dr. M.S. Eslami were: Drs. Abbot, Ahamed, Ahrens, Alisberg, Beck, Bobruff, Czarsty, Dardick, Freedman, Friedberg, James, Kamens, McDonnell, Mendillo, Petrie, Ragusa, Reyelt, Jr., Scheer, Sullivan, Jr., Sweet, Villa, Waldron and Zlotsky.

Also present: Dr. Magauran, Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Sullivan, Mr. Tomat (FCMA), Mr. Meister (NHCMA), Mr. Coffey (HCMA), and Mrs. Eslami (President, Auxiliary).

Absent were: Drs. Bonner, Canzonetti, Concannon, Doctor, Fabro, Kaess, Orphanos, Sadowski, Sharon, Seide and Whalen, Jr.

Reports From Physicians Serving on State and Federal Agencies

Dr. Kamens, a member of the 14-member Task Force on the Prospective Payment Systems for Hospitals, provided a summary report on the 12 weeks of negotiations concerning some 20 issues. Voting results of the task force, whose members included the three members of the Commission on Hospitals and Health Care (CHHC), four state legislators, representatives of industry, insurance, labor, the hospital association, and the medical society, came as no surprise. The end result being a DRG-type system for all-payers in Connecticut.

The implementation of this fixed-priced system commences with the hospital commission preparing draft regulations by November 15th, followed by a public hearing in December. After the hearing, the CHHC must rewrite the regulation and send the final version to the attorney general's office by January 4, 1985. The regulations then go before the legislature's Regulations Review Committee for final approval by April 15, 1985. Hospitals will utilize the regulations for preparation of their budgets effective on October 1, 1986. The system's base year is 1984 and subsequent budgets will be formulated upon hospital cost reimbursement based data that will be collected and analyzed during that period.

Dr. Kamens highlighted key areas of compromise including the allowance of an inflation increment of 1 percent, and provisions to budget funds to cover costs due to charity services and direct medical education. Areas not supported by the task force include intensity of service and indirect medical education costs. Medicare and Blue Cross/Blue Shield were provided with discounts under the system. After four years, however, the Blues may lose that status.

Concerning the issue of peer review, Dr. Kamens indicated that a compromise was voted, at the insistence of representatives of insurance carriers and industry, that peer review will be accomplished by peer review "organizations," with confidentiality of records. However, an additional compromise in the proviso calls for access to their own employees records in terms of utilization and services by individual corporations.

In other business, Mr. Tomat noted that investors are proposing a For-Profit HMO to provide services in the tri-state area including the Fairfield area.

The Staff Report prepared by Mr. Fiorentino was accepted as information.

Report on Connecticut Medical Insurance Company (CMIC)

Jerome K. Freedman, M.D., President of the Management Board (CMMI) of the new physician owned captive insurance company, reported on CMIC developments. He apprised the Council that 922 physicians had become policyholders (New Haven—231, Hartford—219, Fairfield—173, New London—119, Litchfield—69, Middlesex—51, Windham—44 and Tolland—16). It was reported that CMIC has collected $6.6 million in capital and approximately $8 million in premiums. Dr. Freedman commended the efforts of Drs. Joseph S. Sadowski and Mehdi S. Eslami in helping to establish CMIC and pointed out that many others also deserved praise for their endeavors. He added that many tasks await the CMIC and CMMI Board, among them the formation of numerous committees and the selection of legal and investment counsel.

It was VOTED to send a letter to AMA Trustee James S. Todd, M.D., from New Jersey who spoke at one CMIC meeting and has served as a valued resource.

Report of The Executive Director

Tim Norbeck reported on several matters:

1. He reviewed for the Council the disappointing situation in Florida where the Florida Medical Association effort for a statewide referendum on tort reform

was denied access to the November ballot by the Florida Supreme Court.

2. Mr. Norbeck mentioned that he was addressing a meeting of the American Association of Retired Persons in Guilford October 18th.
3. CSMS staff members are preparing, in conjunction with legal and legislative counsel, an aggressive tort reform package which will be considered at the CSMS Committee on Legislation meeting on October 24. Staff and Jerome Bobruff, M.D., (Chairman of the CSMS Committee on Legislation) are also planning to meet with the executive committee of the Orthopedic Section and CONNTORTS about tort reform.
4. Tim Norbeck and Ray Sullivan had attended a meeting on tort reform two nights earlier hosted by James Pattillo, M.D. of the Hartford County Medical Association. Three legislators were present, and the meeting was most productive.
5. There is a meeting of the Podiatry Board on November 7, 1984, to consider podiatry efforts to expand their scope of practice to the ankle. CSMS has protested that procedure and its legal counsel, with staff, is preparing an appropriate and emphatic response.

Medicare Freeze Follow-Up

The Medicare Freeze, as embodied in the Deficit Reduction Act of 1984, was discussed along with the AMA's unsuccessful attempt for a temporary injunction. It was mentioned at the October 13 meeting of the Council of New England Medical Societies (CNEMS) that the new assignment rates in numerous states had plummeted as a result of the Medicare Freeze.

AMA will have posters and brochures ready for distribution in early November for display in physicians' offices which will explain why a physician has chosen not to sign a participating agreement with the government and assuring patients that their care will not be interrupted.

Hartford County Medical Association (HCMA) Resolution—RE: Medicare

Roger S. Beck, M.D., reported on a recent meeting of the United Seniors for Action that he and Drs. Burton Meisner and Norman Alisberg had attended. A resolution subsequently passed by the HCMA Board of Directors as a result of that meeting was discussed and the following resolve was VOTED by the Council for submission to the CSMS House of Delegates.

RESOLVED,

That the House of Delegates of the Connecticut State Medical Society urges its members to accept Medicare assignment for any medicare patient who is unable to afford a physician fee.

CSMS Ad Hoc Committee to Study Physician Reimbursement for In-Hospital Care of Patients: Prospective Pricing Systems: Fee Schedules for Physicians; and All-Payers Legislation

Guy W. Van Syckle, M.D., discussed the meeting held by his committee on September 24th.

It was VOTED that the following items be referred to the CSMS House of Delegates along with an expanded version of the various physician reimbursement systems.

1. That CSMS inform its membership of the types of physician reimbursement and payment systems being considered by the Federal Government and other third party payers and that the staff keep the Council and members apprised of future developments.
2. That CSMS, in liaison with the AMA continue to monitor the new proposals for physician reimbursement for data to determine the effect on all aspects of medical care and medical ethics.
3. In order to deal effectively with these systems, CSMS encourage its members to be informed as individual physicians and as members of organized medicine; that CSMS develop constructive liaison with the executive and legislative branches of government and with business/industrial coalitions; that CSMS develop meaningful public relations programs; and that CSMS develop constructive legislative programs.

It was also VOTED that the CSMS Committee on Statewide Medical Planning be given the temporary responsibility to monitor effects of the all-payer bill on the quality of medical care.

Medicare Reimbursement Policy of Connecticut General, Inc.

Brendan G. Magauran, M.D., Chairman of the CSMS Committee on Third Party Payments, reported to the Council that physicians had expressed concern that Medicare was making arbitrary judgments on what care was necessary for patients and that bills were being adjusted arbitrarily.

It was VOTED to refer the subject back to the committee for further study, with the suggestion that they meet with Connecticut General to obtain further clarification of the policies and report back to the Council.

Committee on Allied Medical Services (Connecticut Joint Practice Committee)

It was VOTED to approve of the following resolution:

WHEREAS, the quality of patient care depends primarily on nurses and physicians; and

WHEREAS, there is often a lack of recognition of the particular skills and contributions of each profession by the other; and

WHEREAS, the years of formal education are most important in establishing a knowledge base for both professions,

BE IT RESOLVED THAT, The Connecticut State Medical Society and the Connecticut Nurses' Association recommend and support efforts by the medical and nursing schools of this state to collaborate wherever possible in fostering understanding of the roles, skills and special knowledge of the two professions, one with the other.

Department of Health Services, State of Connecticut

It was reported to the Council that the Department of Health had requested CSMS to submit nominees to represent the Connecticut State Medical Society on an Advisory Committee to help draft statutory or regulatory language to address the disposal of fetal tissue.

It was VOTED to submit the names of Drs. Romeo Vidone, Melvyn Rapoport, Martin Nadel, and John Gibbons to serve on the Advisory Committee to the Department of Health.

Nominations for Positions on AMA Councils

It was VOTED to send a letter to the AMA Board of Trustees on behalf of Grant Rodkey, M.D., (Massachusetts), who is a candidate for re-election to the AMA Council on Medical Service.

It was VOTED to urge the AMA Board of Trustees to give Thomas Ballentine, M.D., the AMA Distinguished Service Award and to send a copy of that letter to the Massachusetts Medical Society and the Neurological Society.

1985 Budget

Following an analysis of the budget, it was VOTED to approve the budget submitted by the Fiscal Subcommittee. It was further VOTED to approve the Fiscal Subcommittee's recommendation that the dues remain at $175.00 and to transmit the budget to the House of Delegates with Council recommendation for approval by the House.

Auxiliary to CSMS

Marilyn Eslami, President, reported on Auxiliary activities and distributed samples of a Mem-Bear-Ship Pencil and a "Look at Me" whale emblem used for the forthcoming Bundle Up Seat Belt campaign and other Auxiliary projects. The Council members applauded her report and the efforts of the Auxiliary.

Liaison Committee with Connecticut Pharmaceutical Association

Joseph Czarsty, M.D., mentioned that a firm in Connecticut was attempting to sell drugs directly to physicians for sale to their patients and that the CSMS Liaison Committee with the Connecticut Pharmaceutical Association urged the CSMS to adopt the AMA's position on the subject. It was VOTED to adopt the following policy statement of the AMA:

1. A physician should not be influenced in the prescribing of drugs, devices or appliances by a direct or indirect financial interest in a pharmaceutical firm or other supplier. Whether the firm is a manufacturer, distributor, wholesaler or repackager of the products involved is immaterial. Reputable firms rely on quality and efficacy to sell their products under competitive circumstances and do not appeal to physicians to have financial involvements with the firm in order to influence their prescribing.
2. A physician may own or operate a pharmacy if there is no resulting exploitation of patients.
3. A physician should not give patients prescriptions in code or enter into agreements with pharmacies or other suppliers regarding the filling of prescriptions by code.
4. Patients are entitled to the same freedom of choice in selecting who will fill their prescription needs as they are in the choice of physician. The prescription is a written direction for a therapeutic or corrective agent. A patient is entitled to a copy of the physician's prescription for drugs, eyeglasses, contact lenses, or other devices as required by the Principles of Medical Ethics and as required by law. The patient has the right to have the prescription filled wherever the patient wishes.
5. Patients have an ethically and legally recognized right to prompt access to the information contained in their individual medical records. The prescription is an essential part of the patient's medical record. Physicians should not discourage patients from requesting a written prescription or urge them to fill prescriptions at an establishmant which has a direct telephone line or which has entered into a business or other preferential arrangement with the physician with respect to the filling of the physician's prescription.

Impaired Physician Legislation

Guy W. Van Syckle, M.D., mentioned that there appeared to be some problems emerging in the Impaired Physician Legislation which had passed the General Assembly this past year. Some physicians have expressed concern over the punitive nature of the bill, and it will be evaluated by the CSMS' Committee on Legislation for possible revision or amendment.

Life Members

It was VOTED to receive for information the list of Life Members which is as follows:

Ralph C. Andrews, M.D., 16 Franklin Street, Norwich (NL) 1/1/84

John J. Korab, M.D., High Street, Higganum (M) 1/1/84

Charles F. Sornberger, M.D., Hampton (W) 1/1/84

Miscellaneous

Public Affairs—William A. Whalen, M.D., President-Elect of CSMS, could not be present for the meeting but sent in a written resolution pertaining to a public affairs program.

It was VOTED to refer the following resolution to the CSMS Committee on Public Affairs for evaluation, proposals and specific cost estimates and report back to the House of Delegates. It is understood that newspaper coverage will be considered along with radio spots:

RESOLVED:

1. That the Council of the Connecticut State Medical Society charge the Committee on Public Affairs to construct a PR Program immediately to address the following topics: (a) DRG's (b) PRO's (c) Medicare participation (d) Malpractice (e) Care of unemployed and needy.
2. That the theme of the discussion involve the individual and collective efforts to maintain access to a high standard of care at a reasonable cost.
3. That the information is circulated by radio on behalf of CSMS on a statewide basis.
4. That the counties be alerted to the program and request that they consider utilizing county media to annunciate in their own personal style their approach and achievement in addressing the items listed in paragraph one.
5. That the Committee on Public Affairs be authorized to expend the necessary funds to carry out this program without delay and report back to the Council at its next meeting.

Liaison Committee with Connecticut Bar Association – Stewart Petrie, M.D., reported on a recent meeting held by the CSMS Liaison Committee with the Connecticut Bar Association in which the principles of cooperation were discussed. One problem area which will have to be addressed is the appropriate compensation for physicians who prepare as witnesses for court appearances and then are delayed or not called. It was VOTED to accept his verbal report as information.

N.B.: *The foregoing is a summary of the preceedings and actions of the Council on October 17, 1984. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

IN MEMORIAM

ABRAHAMS, MEYER, Tufts, Medical College, 1931. Dr. Abrahams was a surgeon in the Fairfield County area since 1935. He was on the surgical staff of Norwalk hospital, where he also had been on the teaching faculty of a post-graduate program in surgery for interns and residents. During World War II, he served in the U.S. Army Medical Corps from 1942 to 1946, when he returned to New Canaan to resume practice. Dr. Abrahams was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died October 11, 1984 at the age of 76.

COHN, SAMUEL H., Boston University School of Medicine, 1934. Dr. Cohn was a surgeon in the Hartford County area since 1938. He was former chief of surgery at Mount Sinai Hospital and past president of the Hartford County Medical Society. Dr. Cohn was chairman of the Insurance Trust of the Hartford County Medical Society and a recipient of its Distinguished Service Award He was an Army veteran of World War II. Dr. Cohn was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died September 29, 1984 at the age of 76.

CONNOLLY, JOSEPH P., Georgetown University School of Medicine, 1936. Dr. Connolly was a radiologist in the Fairfield County area since 1937. He was on the staff of Norwalk Hospital for many years and before his retirement in 1975, Dr. Connolly was director of the Department of Radiology at St. Joseph's Hospital in Stamford as well as president of the medical staff. He was a veteran of World War II and was a radiologist to the 81st Station Hospital. Dr. Connolly was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died September 19, 1984 at the age of 74.

SCHNEIDER, WILLIAM, George Washington Medical School, 1930. Dr. Schneider was a general practitioner in the Tolland County area since 1931, and was on the staff of Rockville General Hospital. He was an Army veteran of World War II. Dr. Schneider was a member of the Tolland County Medical Association, the Connecticut State Medical Society and the American Medical Association; died September 30, 1984 at the age of 79.

STORMS, WILLIAM, Harvard Medical School, 1930. Dr. Storms was a general practitioner in the Hartford County area since 1932. He was a member of Hartford Hospital Staff, retiring in 1975 and was a recipient of an award for excellence from the American Academy of Family Practice of which he was a member. Dr. Storms was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died October 9, 1984 at the age of 80.

WIRTH, MICHAEL N., Ludwig Maximiliams University, Germany, 1952. Dr. Wirth was a pediatrician in the New Haven County area since 1957. He was on the staff of the Hospital of St. Raphael, Yale New Haven Hospital and Griffin Hospital. Dr. Wirth was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died September 17, 1984 at the age of 62.

PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

ANESTHESIOLOGY

Board certified/eligible Anesthesiologist needed in a modern progressive hospital located in northwest Connecticut. Reply in writing with curriculum vitae and references to President, Sharon Hospital, Sharon, CT 06069.

EMERGENCY MEDICINE

A full-time position available in modern, well-equipped Emergency Room. 73 bed hospital in beautiful northwestern Connecticut. Contact Larry Ward, M.D., Director of Emergency Services, Winsted Memorial Hospital, 115 Spencer St., Winsted, CT 06098.

FAMILY PRACTICE

Family practitioner with larger, modern office in small community is looking for Associate leading to partnership. Write to: David L. Wasley, M.D., P.O. Box 27, Terryville, CT 06786.

BC/BE for progressive group practice in Western Connecticut. High growth area; excellent family life. Send CV to Brookfield Family Medicine Center, 940 Federal Rd., Brookfield, CT 06804.

INDUSTRIAL MEDICINE

Internist: Major corporation, Southern New England, seeks ambitious, bright, motivated, BC physician. Full-time, subspecialty interest cardiology preferable. Opportunity for clinical practice as well as Corporate and Occupational Medicine. Unique opportunity for growth, career development. Attractive salary and benefits. Write to: IND/SSM, c/o CSMS.

INSTITUTIONAL MEDICINE

Physicians—ER, IM, FP. Either BC/BE for expanding physicians owned operated episodic care clinics in Connecticut. Join other excellent physicians, take part in ID and other ambulatory care studies. Competitive salary. Directorship and stock options available. Seeing more than 100,000 visits per year combined. Filling positions now for January and July 1985. Write, Immediate Medical Care Center, 850 Silas Deane Highway, Wethersfield, CT 06109.

Primary care M.D.s needed for freestanding emergency centers in Connecticut. Family Practice/General Practice/E.R. experience desirable. Full and part-time positions available days, evenings, and weekends. $50,000-$60,000 annual salary for 40-hour week depending on experience/qualifications, with option to become part-owner. Direct resumes/inquiries to: Dr. Edward Ewald, 1 Corporate Drive, Windsor Locks, CT 06096.

HOSPICE PHYSICIAN. Position available to be part of the medical staff of the nation's first hospice. The Connecticut Hospice is a JCAH accredited hospital with a 44 bed inpatient facility and a hospice based home care program of 50 patients. Excellent opportunity for a physician interested in palliative care. Connecticut License required prior to employment. Board certification preferred. Full-time position but part-time applicants may be considered. Please C.V. to Mr. John M. Stober, Director of Human Resources, The Connecticut Hospice, Inc., 61 Burban Drive, Branford, CT 06405. An equal opportunity employer.

INTERNAL MEDICINE

Internist to join three others in primary care. Central New Haven. Board eligible. Candidate may be recently trained or experienced practitioner. Write to: IM/MC, c/o CSMS.

OPHTHALMOLOGY

We are seeking a board certified ophthalmologist to develop a private practice in this attractive community of 40,000 in central Connecticut. Financial guarantee and other assistance offered. Contact President, Bradley Memorial Hospital, Meriden Ave., Southington, CT 06489.

OTOLARYNGOLOGY

Excellent private practice opportunity for board certified ENT specialist in lovely northwestern Connecticut community of 12,000 only 45 minutes from Hartford. Service area population of approximately 35,000. Fully accredited 73 bed hospital with superior medical staff. Contact Mr. Paul E. Graff, President, Winsted Memorial Hospital, 115 Spencer St., Winsted, CT 06098.

PEDIATRICS

Pediatrician needed to join long established and very successful pediatric practice in Bristol, CT. 57-year-old soloist wishes to pursue additional postgraduate medical education. Quality practice leading to full partnership and eventual ownership. Write, CSMS, c/o PED/GJ.

WANTED: To buy a busy pediatric practice in Connecticut. Contact, S.S. Rajaram, M.D., 1405 W. 4th St., Gillette, WY 82716 or phone 307-682-1782 in evenings.

PRACTICE FOR SALE

Internal Medicine two year old practice in Hartford available for sale; terms negotiable. Write PRAC/DAB, c/o CSMS.

Internal medicine. Well established practice available March 1, 1985. Fully equipped office in medical building in Hartford. St. Francis hospital area. Write physician, P.O. Box 7-516, West Hartford, CT 06107.

Pediatrics. Active practice in growing community in Fairfield County. Fully-equipped office. Town of 35,000 served by two pediatricians. Five minutes to three major hospitals. Will introduce. Address inquiries to CSMS, PED/SEK.

PHYSICIANS WISHING TO PRACTICE IN CONNECTICUT

ANESTHESIOLOGY

Aug. '85. Age 32. Presently in practice. FLEX; E.C.F.M.G. AB elig. MD, Far Eastern University Hospital, Philippines; Int. and Res., Brookdale Hospital Medical Center, Brooklyn, NY. Prefers a group or associate type practice in a medium to large-sized community. Write, Howard Yap Ang, M.D., 7-29 Hegeman Ave., Apt. 3-A, Brooklyn, NY 11212.

DERMATOLOGY

July '85. Age 30. Nat'l bds. AB elig. MD, St. Louis University, St. Louis, MO; Int., Northwestern University, Chicago, IL; Res., Henry Ford Hospital, Detroit, MI. Prefers specialty or multi-specialty group incorporating a 20 to 30 hour week in a medium-sized community. Write, Catherine A. Nordby, M.D., 871 Beaconsfield, Grosse Pointe Park, MI 48230.

EMERGENCY MEDICINE

July '85. Age 30. Presently in practice. Nat'l bds. AB elig. MD, St. Louis University, St. Louis, MO; Int., Res. and Fellowship, Henry Ford Hospital, Detroit, MI. Preferences are institutions with emergency medicine residency, large trauma centers and/or work to continue research, in a large-sized community. Write, Gerard B. Martin, M.D., 871 Beaconsfield, Grosse Pointe Park, MI 48230.

FAMILY PRACTICE

July '85. Age 27. Nat'l bds. AB elig. MD, Wright State University, Dayton, OH; Int. and Res., Maine-Dartmouth Family Practice, Augusta, ME. Interested in full or part-time position with a group, associate, institutional or industrial type practice in a small to medium-sized community. Write, Paul D. Smith, M.D., P.O. Box 226, South China, ME 04358.

July '85. Age 36. FLEX. M.B.B.S., T.N. Medical College, Bombay, India; Int. and Res., Medical Center of Central Georgia, Macon, GA. Prefers employment on salary basis with HMO or hospital base in a medium-sized community. Write, Kamrudin Mithani, M.D., 3540 D. Lake Terrace Place, Macon, GA 31204.

INTERNAL MEDICINE

Nov. '84. Licensed in Connecticut. Presently in practice. Age 32. Nat'l bds. AB elig. MD, Hahnemann Medical College; Int. and Res., Danbury Hospital, Danbury, CT. Prefers group or institutional type practice in the southern section of Connecticut. Write. CSMS, DR/IM.

Sept. '84. Age 76. Licensed in Connecticut. AB cert. MD, New York University Medical School; Int. Mt. Sinai Hospital, New York, NY. Private practice from 1935-1974; Olin Corp. physician from 1975-1984. Desires group, institutional, industrial or teaching type of practice. Write, Israel A. Schiller, M.D., 74B Dakota Lane, Stratford, CT 06497.

Nov. '84. Age 29. Nat'l bds. AB elig. MD, University Central del Este; Int. and Res., Mt. Sinai Services, City Hospital Center at Elmhurst, Elmhurst, NY. (Fifth Pathway Program with Long Island Jewish-Queens Hospital Center). Prefers group or associate type practice in a medium-sized community. Write, Charles Gelfman, M.D., 123-33 83rd Ave., Kew Gardens, NY 11415.

July '85. Age 28. Nat'l bds. AB elig. MD, Rutgers Medical School; Int. and Res., Hartford Hospital, Hartford, CT. Prefers group or associate type practice. Write, Frances B. Gurtman, M.D., 38 Beacon St., Apt. B2, Hartford, CT 06105.

July '85. Age 33. Licensed in Connecticut. Presently in practice. AB elig. MD, University Autonona of Guadalajara, Mexico; Int. and Res., SUNY Downstate/Kings County Hospital (Brooklyn). Particularly, but not exclusively, interested in areas in western or central Connecticut with a group or associate type practice. Write, RKF/IM, c/o CSMS.

July '85. Age 28. Nat'l bds. AB elig. MD, University of Medicine and Dentistry of New Jersey Medical School, Newark, NJ; Int. and Res., Geisinger Medical Center, Danville, PA. Prefers a group or associate type practice in a medium-sized community. Write, William R. Betz, M.D., Ridgeview Eastlawn, Box 122, Danville, PA 17821.

July '85. Age 28. Licensed in Connecticut. Nat'l bds. AB elig. MD, S.U.N.Y. at Buffalo, NY; Int. and Res., University of Connecticut Health Center, Farmington, CT. Primarily interested in office based practice (group or assoc.) in a small to medium-sized community. Write, Roger J. Beneitone, M.D., 17 Arnold Way, West Hartford, CT 06119.

GASTROENTEROLOGY. July '85. Age 30. Nat'l bds. AB cert. MD, Mount Sinai School of Medicine, New York, NY; Int. and Res., Beth Israel Medical Center, New York, NY; Fellowship, North Shore University Hospital, Manhasset, NY. Prefers group or associate type practice in a medium to large-sized community. Write, Clifford J. Appel, M.D., 10 Wooleys Lane, Apt. 1C, Great Neck, NY 11023.

GASTROENTEROLOGY. April '85. Age 44. Licensed in Connecticut. Presently in practice. Nat'l Bds. AB cert. MD, University of Missouri; Int., Kings County Hospital, Brooklyn, NY; Res., Kings County Hospital and University of Minnesota Hospitals; Fellowship, Hartford Hospital (Yale affiliated GI). Prefers group or associate type practice in medium to large-sized community. Wishes to purchase a practice in greater New Haven. Write, Michael A. Rosenthal, M.D., 4808 Longridge Ave., Apt. 112, Sherman Oaks, CA 91423.

GASTROENTEROLOGY. July '85. Age 31. FLEX. AB cert. (IM). AB elig. (GI). MD, Int. and Res., Baylor College of Medicine, Houston, TX; Fellowship, Georgetown University, Washington, DC. Prefers solo, group or associate type practice in a medium to large-sized community. Write, Kenneth R. Feuer, M.D., 3120 Parkway, Cheverly, MD 20785.

PULMONARY. Aug. '85. Age 32. Nat'l bds. AB cert. (IM); AB elig. (PUL). MD, Padua University, Padua, Italy; Int., Barberton Citizens Hospital, Barberton, OH; Res., Kettering Medical Center, Dayton, (IM); Fellowship, Memorial Sloan Kettering Cancer Center, NY (Critical Care). Prefers group, associate, institutional or industrial type practice. Write. Gianfranco Umberto Meduri, M.D., 430 East 67th St., Apt. 9C, New York, NY 10021.

OPHTHALMOLOGY

July '85. Age 20. Nat'l bds. AB elig. MD, University of Connecticut School of Medicine, Farmington, CT; Int. and Res., Geisinger Medical Center, Danville, PA. Prefers group or associate type practice in a medium-sized community. Write, Peter J. Famiglietti, M.D., Box 76 R.D. #5, Danville, PA 17821.

ORTHOPEDIC SURGERY

July '85. Age 30. Licensed in Connecticut. Nat'l bds. AB elig. MD, University of Maryland; Int., Hartford Hospital, Hartford, CT; Res., University of Connecticut Health Center, Farmington, CT. Prefers group type practice in a large-sized community. Write, CSMS, ORTHO/TPM.

July '85. Age 29. Nat'l bds. AB elig. MD, Rutgers Medical School, New Jersey; Int., Albert Einstein College of Medicine, New Jersey; Res., (Ortho) Rutgers Medical School. Wishes group or associate type practice. Write, Bruce P. Young, M.D., 188-D Cedar Lane, Highland Park, NJ 08904.

PATHOLOGY

Negotiable. Age 36. Presently in practice. Nat'l bds. AB cert. MD, University of Washington, Seattle, WA; Int., Kern County General Hospital, Bakersfield, CA; Res., Santa Clara Valley Medical Center, San Jose, CA. Strong community hospital background. Prefers solo, group or associate type practice in a medium-sized community. Write, James R. Vasser, M.D., 7816 Summerplace Drive, Citrus Heights, CA 95621.

PEDIATRICS

July '85. Age 28. Nat'l bds. AB elig. MD, University of Medicine and Dentistry of New Jersey, Newark, NJ; Int. and Res., Medical College of Virginia, Richmond. VA. Prefers a group type practice. Write, Charles H. Geneslaw, M.D., 8372 Loveridge Court, Richmond, VA 23229.

RADIOLOGY

July '85. Age 33. Nat'l bds. AB elig. MD, University of Arizona, Tucson; Int., University of Connecticut, Farmington, (Medicine); Res., Medical College of Wisconsin, Milwaukee. Desires group practice. Write, Brian S. Puglisi, M.D., 5188 N. Lovers Lane #3, Milwaukee, WI 53225.

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For further information, write or call:

Navy Medical Programs
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